

Safe and Sustainable by Design (SSbD) Revised Methodological Guidance (2026)

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Abstract

This Methodological Guidance provides support for the application of the 2025 revised safe and sustainable by design (SSbD) framework for chemicals and materials. It builds on the previous 2024 SSbD Methodological Guidance.

The SSbD framework combines the methodologies of “Safety Assessment” (SA), “Environmental Sustainability Assessment” (ESA) and Socio-economic Sustainability Assessment (SEA), which have different goals, scope, and terminology.

This Methodological Guidance explains how to apply the 2025 SSbD framework and provides indicative “Frequently Asked Questions” replies to the feedback collected during the several stakeholder consultations conducted during the testing period, and the two SSbD Testing Phase questionnaires, where relevant. These various consultation stages have usefully contributed to the progressive refinement of both the SSbD framework and to this guidance document.

This 2026 edition of the SSbD Methodological Guidance presents in greater detail a method for conducting the scoping analysis and discusses why, and how, it is important to correctly frame the subsequent safety and sustainability assessments in an iterative and tiered approach. Following on, thematic sections specifically address aspects of the two principal disciplines of the framework: safety assessment and environmental sustainability assessment, including a more detailed section on the socio-economic assessment.

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Executive summary

Policy context

With the European Green Deal (European Commission, 2019) the European Commission (EC) aimed to transform the European Union's (EU) economy to support a more sustainable future and to implement [the United Nations' Sustainable Development Agenda 2030](#). Among the objectives of the Green Deal is the Zero Pollution Ambition (European Commission, 2021b). To achieve this goal, a set of actions were outlined in the Chemicals Strategy for Sustainability (CSS) (European Commission, 2020). Specifically, within the CSS action 2.1 - Innovating for safe and sustainable EU chemicals, sub-action 2.1.1 aims at promoting 'safe and sustainable by design' chemicals, while sub-action 2.1.2 aims at achieving safe products and non-toxic material cycles.

With the Competitiveness Compass for the EU (EC, 2025a) the European Commission (EC) emphasised the importance of closing the innovation gap to drive sustainable and long-term growth. It highlights the importance of innovation in boosting the competitiveness of the EU's chemical industry, together with the protection of human health and the environment. The Competitiveness Compass also underlines the need to look at the supply of critical chemicals and to invest in technologies that will matter in tomorrow's economy, such as advanced materials.

On 6 March 2026, the EC adopted a Recommendation on revising the European assessment framework for "safe and sustainable by design" (SSbD) chemicals and materials (EC, 2026a), to support the implementation of the Chemical Industry Action Plan (EC, 2025b), the Clean Industrial Deal (EC, 2025c), and many other strategies and action plans supporting the clean competitiveness ambitions. The scientific-technical basis for this Recommendation, i.e., the revised SSbD framework, henceforth called 'the SSbD framework', was developed by the EC's Joint Research Centre (JRC) (Garmendia Aguirre et al., 2025).

SSbD Methodological Guidance - 2026 Update

- The Methodological Guidance (henceforth 'the Guidance') updates the 2024 Methodological Guidance publication (Abbate et al., 2024) and clarifies certain aspects of the application of the updated Dec 2025 SSbD framework (Garmendia Aguirre et al., 2025a). Throughout, it must be emphasised that the SSbD framework is a voluntary approach combining several disciplines, primarily safety assessment and sustainability assessment, which differ, among others, in scope, established methodologies, framing and terminology.
- The Guidance is intended for professionals wishing to apply the SSbD framework in the research and innovation (R&I), continuous improvement and pre-market areas to develop new chemicals, materials, processes and/or products. The Guidance should also be useful to Member States' agencies and ministries, regional entities, civil society and environmental NGOs, trade associations and developers at various levels of funding programmes supporting such innovations and improvements.

Related JRC work

The JRC has been involved in assessing the safety of chemicals since the early 1990s, and in addition has developed methodologies for sustainability assessment for decades.

After the adoption of the European Green Deal and the CSS, the JRC was asked to develop a SSbD framework that could help to evaluate the level of safety and sustainability for chemicals and materials. The resulting framework (Caldeira et al., 2022a) was developed based on a review of other existing frameworks (Caldeira et al., 2022b) and was integrated into the EC Recommendation establishing a first European assessment framework for ‘safe and sustainable by design’ chemicals and materials to support the implementation of the CSS (EC, 2022). The JRC tested the framework by performing a complete case study (Caldeira et al., 2023) and by assisting industry stakeholders to perform two additional case studies. The SSbD framework has been promoted and consulted upon, especially via two rounds of technical testing with SSbD users, conducted during 2024 and 2025, as well as via an Open Public Consultation (using EU Survey) in 2025, supplemented by optional additional in-depth stakeholder feedback during the same period. The JRC revised the SSbD framework in 2025 (Garmendia Aguirre et al., 2025a), based on the feedback received from practitioners and stakeholders.

Quick guide

The Guidance document starts with a short Introduction (Section 1) and an overview of SSbD in a nutshell (Section 2). Thereafter it follows the structure of the SSbD framework: Section 3 presents the scoping analysis and its outcome, the SSbD scenarios, that supports to correctly frame the subsequent safety and sustainability assessments. Sections 4 to 6 specifically address aspects of the safety assessment, environmental sustainability assessment and the socio-economic assessment. Finally, the Guidance discusses the improved Evaluation (Section 7) and Documentation (Section 8) part of the SSbD framework, to close the implementation cycle.

1. Introduction

With the European Green Deal (EC, 2019) the European Commission (EC) aimed to transform the European Union's economy to support a more sustainable future and to implement the United Nations' Sustainable Development Agenda 2030. Among the objectives of the Green Deal is the Zero Pollution Ambition (EC, 2021b). To act towards achieving this goal, a set of actions was outlined in the Chemicals Strategy for Sustainability (CSS) (EC, 2020). Specifically, within the CSS action 2.1 - Innovating for safe and sustainable EU chemicals, sub-action 2.1.1 aims to promote safe and sustainable by design chemicals, while sub-action 2.1.2 has the objective of achieving safe products and non-toxic material cycles. In 2022, the EC adopted a Recommendation establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials (hereafter SSbD) in R&I activities to support the implementation of the CSS (EC, 2022). The scientific-technical basis, i.e., the SSbD framework, upon which the Recommendation is based, was developed by the Joint Research Centre (JRC). The 2022 SSbD framework was applied to case studies by the JRC (Caldeira et al., 2023) and tested by stakeholders.

The active involvement of stakeholders throughout the development and testing of the framework has been crucial to revise the framework and to ensure its applicability and workability. The revised SSbD framework, henceforth called 'the SSbD framework', has been developed after considering feedback received from stakeholders and users during the two SSbD testing phases and discussions at the several related workshops and ad hoc submissions.

Stakeholders have indicated that one of the principal challenges regarding the implementation of the SSbD framework concerns difficulties in implementing the framework along the innovation process (Garmendia Aguirre et al., 2025b). Thus, the main goal of the Guidance **is to provide explanations and examples, and to present guidance to address this challenge.**

This Guidance, which is an update of the previous SSbD Methodological Guidance published in 2024 (Abbate et al., 2024), is **intended for professionals wishing to apply the SSbD framework.** This includes innovators working in the research and innovation (R&I) areas and those who develop new chemicals, materials, processes, and/or products, or who are exploring how to optimise in these same areas. In addition, it is intended also for practitioners who examine the safety and sustainability performance of these developments, as well as wider stakeholders (NGOs, agencies, trade associations, etc).

The SSbD framework and this guidance refer to 'SSbD Practitioners', meaning any individual or group of professionals from the diverse disciplines required to implement the Safe and Sustainable by Design (SSbD) approach (e.g., innovators, chemists, toxicologists, materials scientists, engineers, and sustainability experts).

An SSbD practitioner is a professional who, regardless of their specific technical background, can adopt a holistic and system-oriented perspective on innovation, thus integrating safety, sustainability, and functionality considerations across the entire life cycle of a chemical, material, process, or product.

The general assumption is that the reader has a detailed familiarity with the **revised Commission Recommendation on SSbD (EC, 2026a)**, the contents of the **revised SSbD framework (Garmendia Aguirre et al., 2025a)** and knowledge on innovation, safety, and sustainability. **Therefore, this Guidance complements the 2025 framework and the 2026 Recommendation.**

2. The SSbD framework in a nutshell

What is the SSbD framework, and is it mandatory? What is the goal of SSbD?

- The SSbD framework is a general approach to steer innovation towards safer and more sustainable chemicals and materials throughout the entire life cycle. The framework can be applied to the development of new chemicals, materials, processes and products or to the re-assessment of those already in existence.
- The application of the SSbD framework is **voluntary**. It combines established safety assessment with sustainability assessment techniques, such as Life Cycle Assessment (LCA) methods.
- The SSbD framework promotes the design, development, production and use of safer and more sustainable chemicals and materials considering their entire life cycle, steering the substitution of hazardous and less sustainable chemicals and materials. The overall goal is to help in preventing pollution whilst also reducing society's environmental footprint.

What does the SSbD framework consist of?

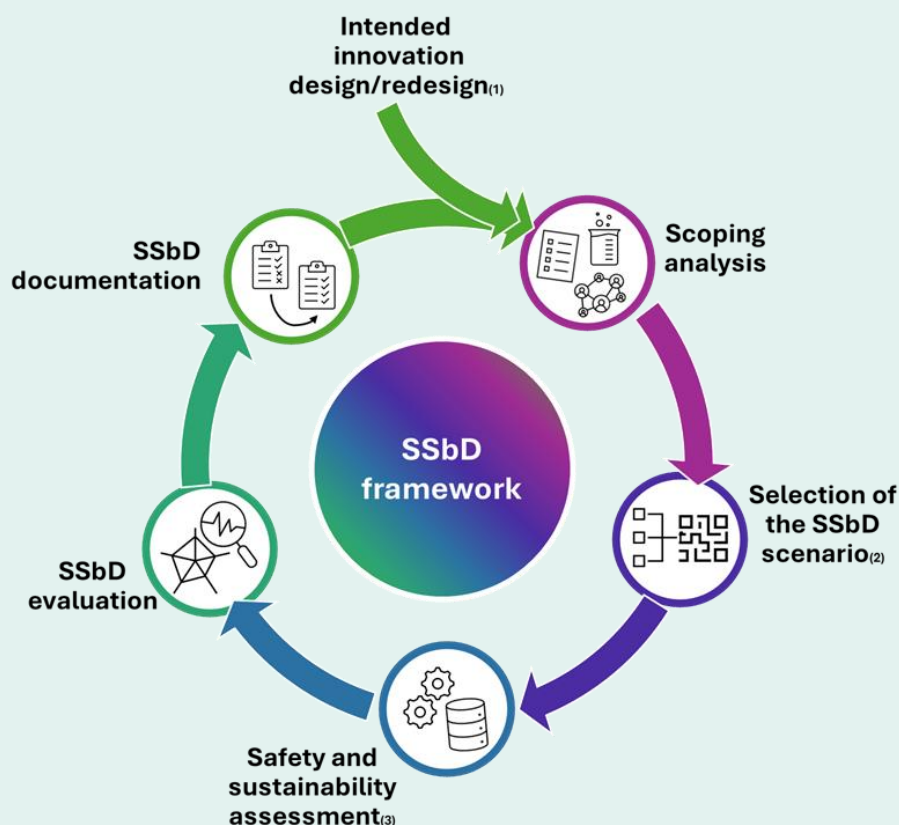
Figure 1 shows the circular structure of the SSbD framework which emphasises the iterative nature of its implementation throughout the innovation process. Below is a brief description of all the components, with detailed explanations provided in the following chapters.

- **Intended innovation - design/ redesign:** The aim of the SSbD is to guide chemicals and materials innovation from the (re)design, along all the innovation stages, scaling up from prototyping, to market readiness. Assessing the innovation in terms of its capacity of delivering safer and more sustainable solutions the

SSbD acts as a compass throughout the innovation process, since **applying design principles in the (re)design phase alone is not enough**. To ensure safety and sustainability it is essential to perform an assessment as means to unveil hotspots and trade-offs, to be addressed during the innovation.

- **Scoping analysis:** defines the objectives, principles and decision rules of the intended innovation. It includes the description of the initial SSbD system under study, the contextualisation of the intended innovation, including the (re)design, and identification of the actors along the life cycle.
- **SSbD scenario:** represents the outcome from the scoping analysis and identifies the entry point to the SSbD assessment, which allows one to tailor the safety and sustainability assessments accordingly.
- **Safety and Sustainability assessment:** includes the holistic assessment of safety and sustainability aspects along the entire life cycle of the chemical/material, for both environmental and socio-economic aspects.
- **SSbD evaluation:** presents the outcome of the safety and sustainability assessment and compares the results in an iterative manner with the objectives, principles and decision rules defined in the scoping analysis. A dashboard to visualise the results, together with approaches to navigate the trade-offs are proposed.
- **Documentation:** proposes a template for recording the implementation of the SSbD framework in a traceable and transparent manner, outlining the actions and objectives for the subsequent iteration.

Figure 1. Overall structure of the SSbD framework



(1) Innovations can be triggered for example by the need of improving existing portfolios, new market/consumer requests, new ambitions and priorities and/or policy priorities
 (2) Key moment where the tailored safety and sustainability assessment is defined according to the outcomes of the scoping analysis
 (3) The safety and sustainability assessment are tailored based on the *selected SSbD scenario*

Source: JRC

What are the main features of the SSbD framework?

- It is **iterative**, mirroring the iterative nature of innovation as a continuous process of planning (scoping analysis), developing, evaluating and refining, and improving ideas through repeated cycles of feedback and adjustment, essential for fostering creativity and adaptability in organizations.
- It has a **tiered** approach. The iterations consider the gradually increasing amount of data generated and collected as the innovation proceeds. Safety and environmental assessments are performed at each iteration to the level of detail that can be achieved with the data available at that point in time.

What are the SSbD principles?

- Safety and sustainability aspects are addressed with a holistic perspective throughout the innovation process.
- Assessments consider the entire SSbD system including chemicals /materials, processes and products under study and their related life cycles.
- The SSbD concept builds on multidisciplinary engagement of the life cycle actors and company experts to ensure that both safety and sustainability are considered throughout the entire innovation.
- The SSbD concept implies transparency of the assessment and traceability of the fulfilment of the principles throughout the entire innovation.

How and when should the SSbD framework be applied? What if there is only incomplete information on the sustainability aspects/ safety elements?

- It is recommended to start applying the framework as early as possible in the innovation process.
- As the application of the framework is iterative, it can begin with the use of available information, using simplified estimation tools and models with narrower SSbD system boundaries, gradually building up and refining the information base over time. A lack, or paucity of in-depth knowledge regarding safety and sustainability information is normal in the early innovation process. As the innovation is progressively refined, it matures in parallel with the completion of information.
- The SSbD Methodological Guidance outlines the way in which the SSbD Practitioner can set the goals and scope and use established and novel Safety and Sustainability assessment means from an early point on to implement the framework.

What are the links between the SSbD and established or upcoming regulatory requirements on safety and sustainability?

- The application of the SSbD framework is voluntary and is oriented towards organisations wishing to consider general corporate responsibility in their innovation processes. Organisations can use the SSbD framework for their own in-house systems, auditing and review processes.
- The framework builds on the same tools as promoted in regulatory requirements but in addition enable the use of innovative approaches, thereby pushing the frontiers of science.

- The voluntary nature implies that there are no guarantees that the implementation of the SSbD framework (i.e. its principles) automatically results in compliance with specific regulatory requirements.
- Nevertheless, the use of the SSbD framework can help to anticipate regulatory needs, e.g. in the search for alternatives for substances that, today, can only be used under time-limited authorisations or exemptions from restrictions.

How does the SSbD framework promote innovation?

The SSbD framework promotes innovation by:

- encouraging the use of appropriate available data and safety assessment and sustainability assessment methods and tools.
- enabling the use of new scientific and technological knowledge together with established assessment methods and tools.
- reinforcing the (re)design of safe and sustainable life cycles for chemicals and materials
- feeding the overall process of corporate and R&D decision-making with new reflections, including information on trade-offs between various aspects: sustainability, safety, as well as socio-economic assessment.
- becoming an element in strategically developing a company's preparedness regarding future legislation that may require the use of "safer and more sustainable chemicals, materials, processes and products" to replace existing concerning ones.

3. Scoping analysis

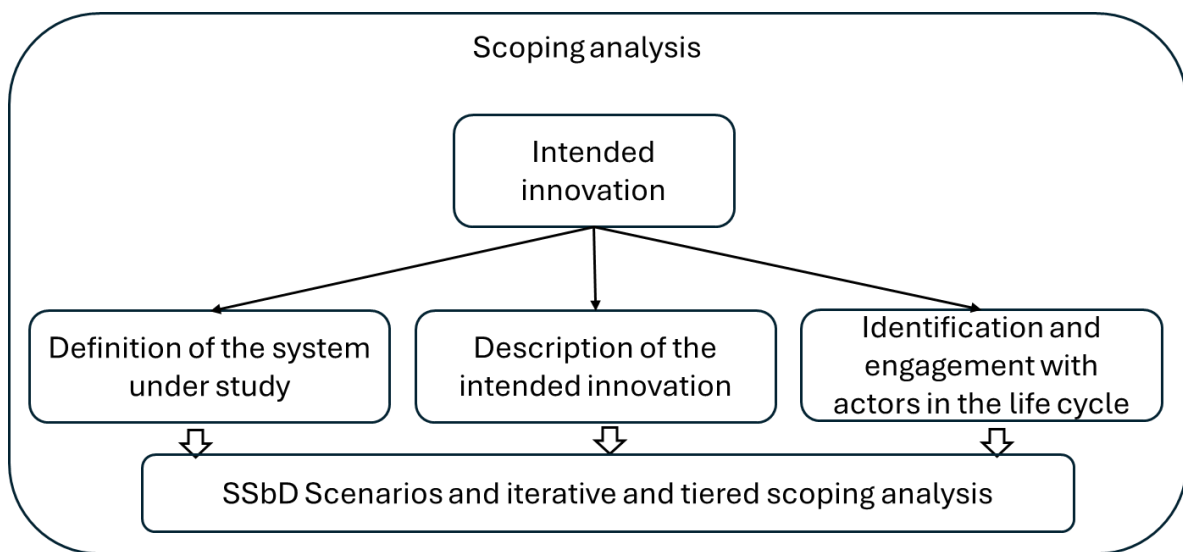
AIM OF THE SECTION:

The scoping analysis contextualises the intended innovation for the implementation of the SSbD framework according to its principles. In the scoping analysis the objectives, principles and decision-making rules of the innovation are defined. It includes the description of the SSbD system, the definition of the intended innovation including the (re)design and the engagement with the actors along the life cycle.

This section describes more in detail:

- The **intended innovation**
- The information needed to define the **SSbD system** to be assessed
- The purpose/objective and nature of the **(re)design** in the SSbD system
- **Engagement with actors** within the SSbD system to apply the framework
- The **SSbD scenarios** and the **iterative** and tiered SSbD scoping analysis

Figure 2. Structure of the scoping analysis section



Source: JRC

3.1. Intended innovation

The intended innovation is contextualised by the scoping analysis. An R&I project can be initiated from different needs, have different objectives, and involve different organisations. For example, the innovation can be initiated by:

- An RTO (Research and Technology Organisation) incorporating an innovative material to an existing product (e.g. a plastic container) to improve its performance in the application (e.g. improving the shelf life of the food in the plastic container).
- A company exploring new bio-based raw materials, or new production processes, to synthesise the same chemical, whilst also improving sustainability aspects.
- A product manufacturer improving the safety, sustainability and performance of the product by changing how it is used or applied.

The scoping analysis has two main functions: (i) to identify relevant aspects for a focused assessment of the innovation, and (ii) to guide the intended innovation towards the progressive fulfilment of the SSbD principles, via simplified, intermediate or full SSbD implementation.

The goal and nature of the innovation – incremental or breakthrough (see SSbD revised framework for the definition, section 6.1), should be considered when implementing the SSbD framework and applying the scoping analysis.

The scoping analysis is an iterative, decision-oriented process that evolves with the maturity of the innovation and progress toward SSbD fulfilment. It allows flexibility, defining how and where safety and sustainability assessments should be conducted, to ensure that they are meaningful and proportionate, at each stage of the innovation process (Garmendia Aguirre et al, 2026a).

Through iterative application, the scoping analysis identifies the appropriate pathways for SSbD implementation. It also establishes milestones and short-term objectives along the decision-making process, to ensure that safety and sustainability assessments remain aligned with other aspects that are central to the innovation being undertaken, such as functionality or technical performance requirements. Each iteration informs subsequent iterations, supporting continuous improvement and alignment with SSbD principles. **At early stages**, uncertainties may be high, related to final application, material composition, manufacturing processes, exposure conditions, and life cycle boundaries. The scoping analysis, therefore, may rely on **limited data and assumptions**; it should be **progressively refined** as the **innovation matures**, more information is gathered and generated and uncertainty decreases.

Structuring the innovation within the SSbD context, via key elements and questions to be answered, results in the outcome of the scoping analysis, namely the relevant SSbD scenario. The resulting **SSbD scenario guides** the focused assessment, evaluation, and decision-making processes of the innovation in the short term, while also identifying the need for the progressive fulfilment of the SSbD principles in the long term, as innovation matures.

The SSbD scenario(s) also support the process of **transparent documentation of the SSbD implementation**, recording the assumptions, methods, evidence, and design decisions made at each stage. Since the scenario(s) evolve across iterations, they naturally reflect the **tiered approach to achieving the completeness of SSbD principles**, progressing from simplified screening to more

comprehensive and quantitative evaluations. This iterative documentation provides traceability of how safety and sustainability considerations were integrated throughout the innovation process.

Problem formulation (Section 4.2) and *Goal and scope definition* (Section 5.3) add granularity to the scoping analysis, to enable focused safety and environmental sustainability assessments, respectively.

3.2. Definition of the system under study

The system definition establishes what exactly is being assessed within the SSbD framework. It establishes the boundaries of the assessment in each iteration.

The system definition encompasses the chemical(s), material(s), process(es), and product(s) considered in each iteration of the SSbD implementation (Figure 3). These elements are interconnected in a value chain and together form the system under assessment.

A substance represents the fundamental chemical unit; substances are combined into mixtures or transformed into materials with specific properties through processes. These chemicals and materials are subsequently integrated into products that deliver a function in the use phase.

Since innovation may introduce changes at any of these elements, the system definition must account for such changes. Once the initial system has been defined, it is important to characterise how the innovation alters substances, processes, and/or products (see Section 3.3 for more details and examples).

The definition of the system should reflect the organisation's position in the life cycle, the maturity of the innovation and the level of SSbD implementation. **At early stages of innovation**, the system definition may be partial and may solely focus on life-cycle stages where the practitioner has direct control or influence, and where the innovation has a direct impact. If the system is defined too broadly, too early, this may lead to high uncertainty and dilute decision relevance. The SSbD practitioner should be aware of this.

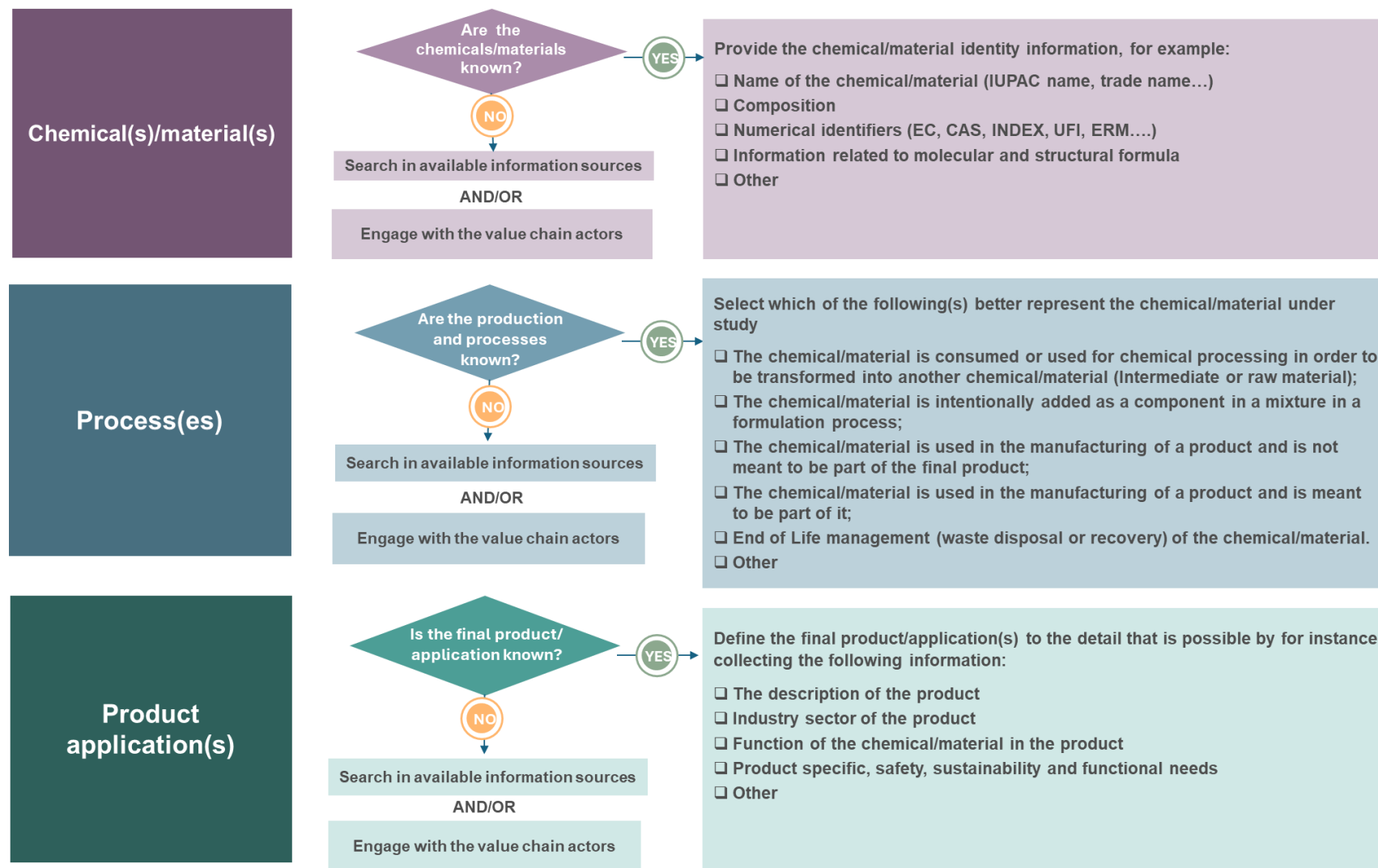
As the innovation matures, the system definition should be progressively improved and refined to better reflect real-life conditions and the engagement across the value chain actors. The system definition should therefore be seen as dynamic, evolving together with the innovation. By the end of the SSbD implementation process, the practitioner should be able to define the full SSbD system.

The system definition should be documented transparently and reviewed at each iteration. The SSbD practitioner should also identify which life-cycle stages are explicitly included, which are excluded and for which reason and the envisaged actions to be included in the subsequent iterations.

Examples of system definitions

- **Early-stage innovation:** A chemical manufacturer defines the system as the synthesis of a novel molecule, including raw material sourcing and synthesis, but excluding downstream uses (product formulation, use phase, end-of-life) in the first iteration, due to a lack of information (unknown applications).
- **Later-stage innovation:** The system is expanded to include incorporation of the molecule into materials and products, consumer use, and end-of-life scenarios based on expected market deployment.

Figure 3. SSbD system elements (chemical/material, process, and product) and information necessary to enable their definition



Source: JRC

3.3. Description of the intended innovation and the (re)design

The description of the **intended** innovation includes information such as the specific **innovation objectives(s)**, the nature of the **(re)design** and, whenever possible, the identification of indicators and the definition of **decision-making rules** and criteria that support the assessment in each iteration. The preliminary identification of potential hotspots along the life cycle can be also identified at this stage.

The SSbD focuses on safety and sustainability performance, and it does not provide guidance on other aspects of innovation. However, it recognises functionality as a key interconnected aspect that needs to be taken into consideration in the SSbD scoping and evaluation (Box 1).

Box 1. Interconnections between safety, sustainability and functionality.

Intrinsic properties—such as reactivity, volatility, and persistence—of chemicals and materials determine how they behave. From these properties comes their functionality: a highly reactive substance may clean or disinfect very effectively, while a substance which is volatile can act quickly by spreading easily. At the same time, those same properties may affect safety and sustainability. For example, high reactivity can create risks for human health, and persistence can lead to long-term environmental pollution.

If the goal of the intended innovation is to improve safety or sustainability—by reducing toxicity or designing a chemical to break down more easily—this would change the intrinsic properties, which can also reduce how well the chemical/material performs. On the other hand, optimising for maximum functionality may rely on properties that increase the hazard or environmental impacts. This creates a constant balance between performance, safety, and sustainability aspects that need to be considered in the evaluation. Importantly, these intrinsic properties are not only determined by the molecular structure but are also influenced by how the chemical or material is produced.

The choice of raw materials, energy use, production conditions, and the presence of impurities or byproducts can affect properties such as durability, stability, and toxicity. For example, a cleaner production process may reduce hazardous impurities, but it might increase costs or limit performance. A process designed purely for efficiency or yield might introduce harmful residues or require more energy. Removing a hazardous additive may improve safety, but that additive might have been responsible for enhancing strength, conductivity, or durability—so performance can decline.

Innovation objectives may focus on a specific functionality, safety or sustainability aspect or a particular life cycle stage (e.g. product/ application) or receptor (e.g. consumers), or combinations thereof. Importantly, goals can be context-specific and may evolve over time, as the implementation of the SSbD progresses.

By defining clear innovation objectives(s), the SSbD practitioner can identify (re)design principles (existing or new) to support the intended innovation. These principles support the definition of (re)design actions, which then explain how the innovation goals will be pursued (Box 2).

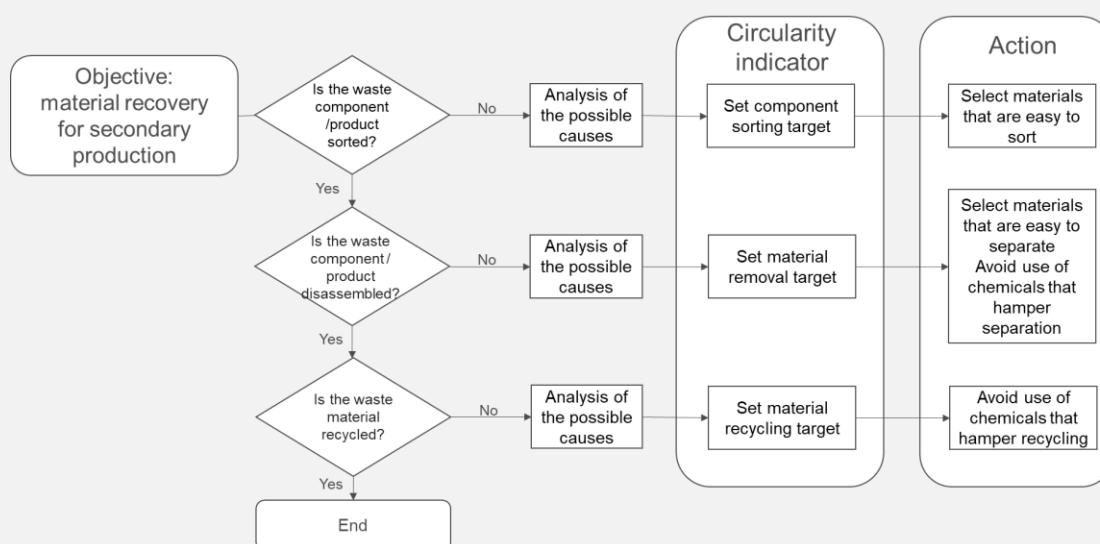
Box 2. Link between the (re)design objectives and actions for the implementation of the SSbD framework in the intended innovation

Recycling and disassembly are crucial indicators to ensure the recovery of Critical Raw Materials, thus avoiding the potential negative environmental and social impacts associated with their extraction and processing. Hence, they have a particularly relevant role in the life cycle assessment.

Figure 4 shows an example of how the ‘Design for end of life’ principle could be considered to capture the circularity aspect of a material embedded in a component or product. The graphic shows how to identify the ‘hotspots’ of the waste management operations and where to place the most effective corrective actions.

Firstly, waste chains should be analysed to identify the ‘gaps’ to achieving greater circularity of the material and related causes (e.g. infrastructural deficiencies, presence of chemicals that hinder the waste management operations, etc). The adoption of the most suitable indicators and targets should guide the company towards the (re)design action. Hence, any actions and target set need to be analysed in the subsequent part of the implementation of the framework by the safety and sustainability assessment.

Figure 4. General flow for implementing the ‘Design for end of life’ principle within the (re)design phase.



Source: JRC

By linking innovation objectives and (re)design actions with the elements of the defined system, the practitioner can align these with the three levels of (re)design, i.e. molecular, process and product defined in the framework (Garmendia Aguirre et al., 2025a). An example for each level is reported below.

Examples of different (re)designs

- Chemical/material (molecular) redesign: Introducing side chains to reduce bioaccumulation potential while maintaining material performance. Redesign of a chemical structure while maintaining the same application. New intrinsic properties are expected and therefore implications in the entire SSbD System are likely.
- Process redesign: Switching from batch to continuous processing, to reduce energy demand and waste. Process redesign to reduce energy consumption without altering the chemical composition. Trade-off implications might arise in the process.

- Product redesign: Encapsulating a hazardous substance (e.g. within a vitreous layer) to reduce user exposure during application. Product redesign that changes the formulation or application method of the product that would affect the exposure profiles. In this context, the protection layer can be designed to minimise the use of Critical Raw Materials (CRM).

Indicators, criteria and decision rules enable the evaluation of whether the intended innovation is moving in the desired direction according to the defined goal(s) in terms of safety, sustainability, and functionality. Such rules follow the maturity of innovation, and they evolve as the implementation of the SSbD progresses, in response to the available information, to feed into the safety and sustainability assessments. Indicators and decision rules may change accordingly from qualitative to quantitative as innovation matures.

Indicators translate innovation goal(s) and actions into measurable or assessable elements. **In early SSbD iterations**, indicators may be qualitative or semi-quantitative and target the specific (re)design actions and decision-making context (screening, comparison between design options, optimisation, etc) corresponding to the level of maturity. As the innovation progresses and more data become available, the assessment should progressively be refined and expanded by complementing the set of indicators. **In later iterations**, full sets of safety and sustainability indicators should be considered, and the assessment relies on more robust quantitative metrics.

Examples of innovation indicators (at the early stages):

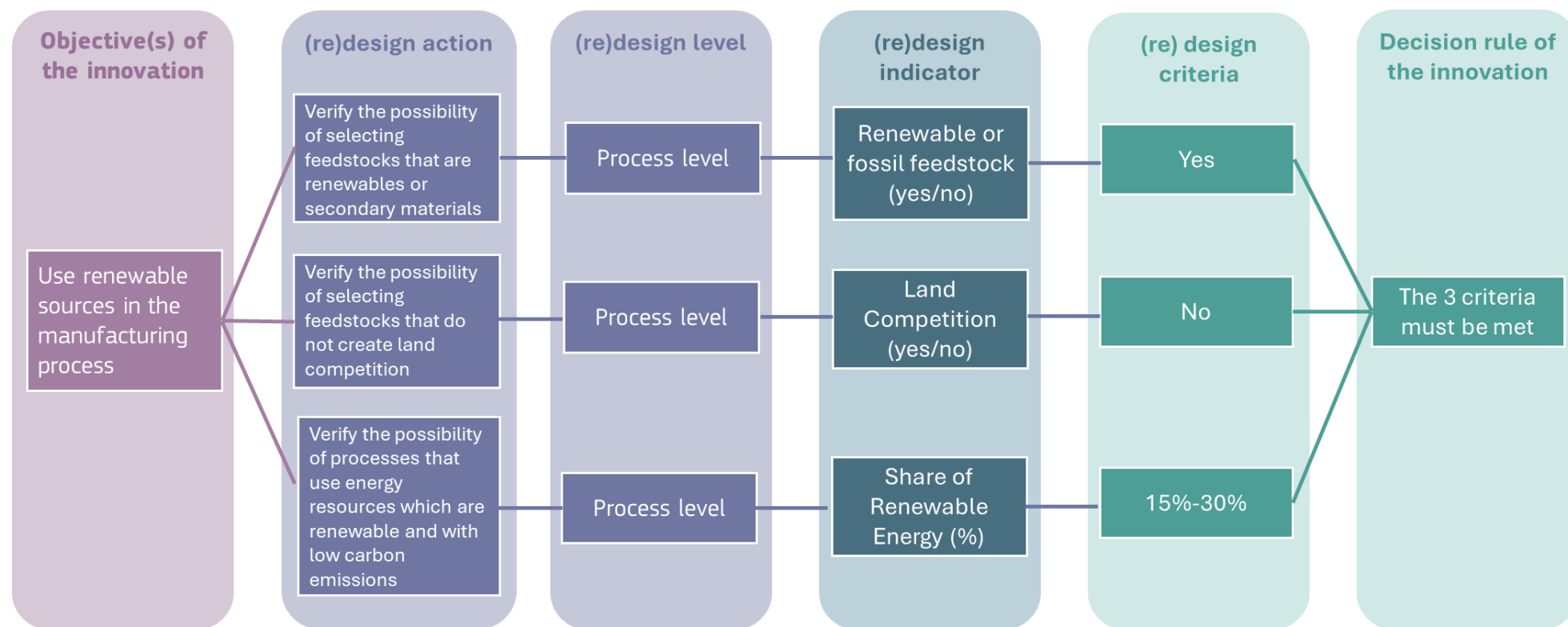
- Safety: specific hazard endpoint or exposure route
- Environmental: Greenhouse Gases (GHG) emissions, energy demand.
- Functionality: durability, efficiency, performance metrics.

Decision-making rules can be chosen to support the evaluation of the assessment results (see Section 7 for more details on the Evaluation). These rules should provide a structured way to interpret indicator results and guide choices under uncertainty, for example: Threshold-based rules, Comparative improvement rules or Exclusion rules (“no-go” criteria). They should be simple in early iterations and enable prioritisation and early red-flag identification, and address more complex logical and sequential decision in later stages. Rules may be qualitative or semi-quantitative.

Figure 5 provides an **example of the definition of the intended innovation** and its elements based on a design principle: specific objectives, (re)design actions and level, the indicators, criteria and decision-making rules or criteria to measure the success of the action towards achieving these objectives.

At this point, it should be remembered that **applying design principles alone is not enough**. To ensure safety and sustainability, it is essential to perform the assessments needed to reveal hotspots and trade-offs, which then must be addressed during the progressive innovation steps.

Figure 5. Potential example on how, based on a design principle, the SSbD Practitioner can define the specific objectives, (re)design action and indicators and decision rules/criteria for the innovation.



Source: JRC

The (re)design will have direct and/or indirect implications in the defined system. For instance, a process (re)design will have direct impact in the safety and/or sustainability of the process itself but may have an indirect impact in the further downstream processes and uses. **At early stages of innovation**, the SSbD practitioner might limit the safety and sustainability considerations to the specific life cycle stage in which the (re)design takes place. **As innovation matures**, consideration needs to be given to how this (re)design affects other life cycle stages, and their safety and sustainability performance. By the end of the SSbD implementation, the overall safety and sustainability performance of the SSbD system should be ensured insofar as it is feasible, considering the possibilities of incomplete data coverage, or the inherent uncertainties or incompleteness of assessment methods.

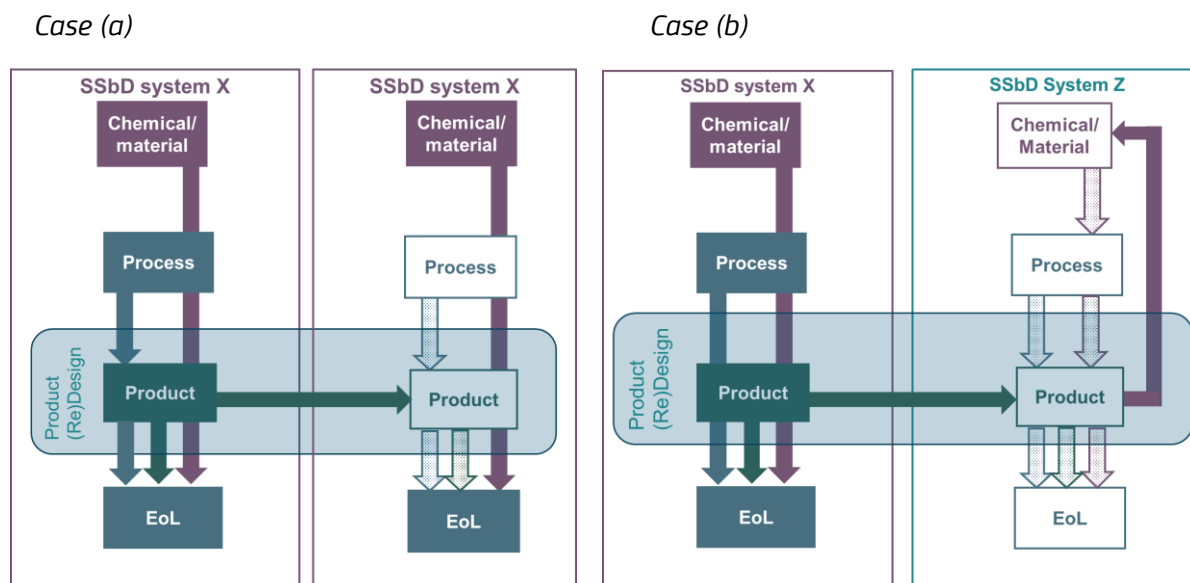
The selection of (re)design action(s) might require the expansion of the initial defined system (see 3.2 for the system definition). The substitution of one chemical/material with another, or an upgrade in a chemical reaction process that would require new technologies, or for existing technologies to be set up differently, should be considered in the assessment. This is done by redefining the system to include such changes.

Examples of changes in the SSbD system:

A paint producer wants to improve safety aspects during the use of a paint placed on the market by reducing the inhalation exposure to the consumer/professional. Different (re)design options can be envisaged, and two of these are:

- a. The paint could be brush painted instead of a spray application (product redesign). Brush or roller application mainly leads to exposure to solvent vapours during application and drying. By contrast, spray application generates fine, respirable aerosols that can penetrate deeply into the lungs, increasing short-term inhalation exposure and airborne dispersion. From an environmental perspective, brush systems concentrate environmental risks in waste and wastewater management, while spray systems pose higher diffuse air-release risks. Thus, even with similar formulations, they require different SSbD considerations (Figure 6(a)).
- b. To enhance the functionality of the new application, some additives in the paint are substituted (i.e., molecular redesign). The **SSbD system changes** via this, since the chemical/material per se under assessment changes. Therefore, the new system needs to be assessed to evaluate its safety and sustainability performance in addition to its technical functionality through the entire life cycle (Figure 6(b)).

Figure 6. Changes in the initial SSbD system, depending on the nature of the (re)design, the initially defined SSbD system X (coloured chemical/material, process, product) might change during R&I projects. Changes of colours illustrate how the initial system component (chemical, process, product) have changed in system Z.



Source: JRC

The (re)design (and the results of the assessment) might trigger questions such as whether there is any variation to the initial system (e.g. chemical/material, process, product), or whether other hotspots may arise from it. The identification of these **hotspots** helps to frame the assessment regarding the potential consequences due to the (re)design action.

Therefore, the SSbD practitioner needs to identify where and how (re)design actions are applied, distinguishing between molecular-level redesign (chemical/material structure, composition), process-level redesign (reaction conditions, solvents, energy inputs) or product-level redesign (formulation, delivery mechanism, use pattern). The practitioner then needs to consider whether the redesign in fact creates a new SSbD system, or if instead it improves the performance of an existing system, and whether indirect implications in other life cycle stages might occur.

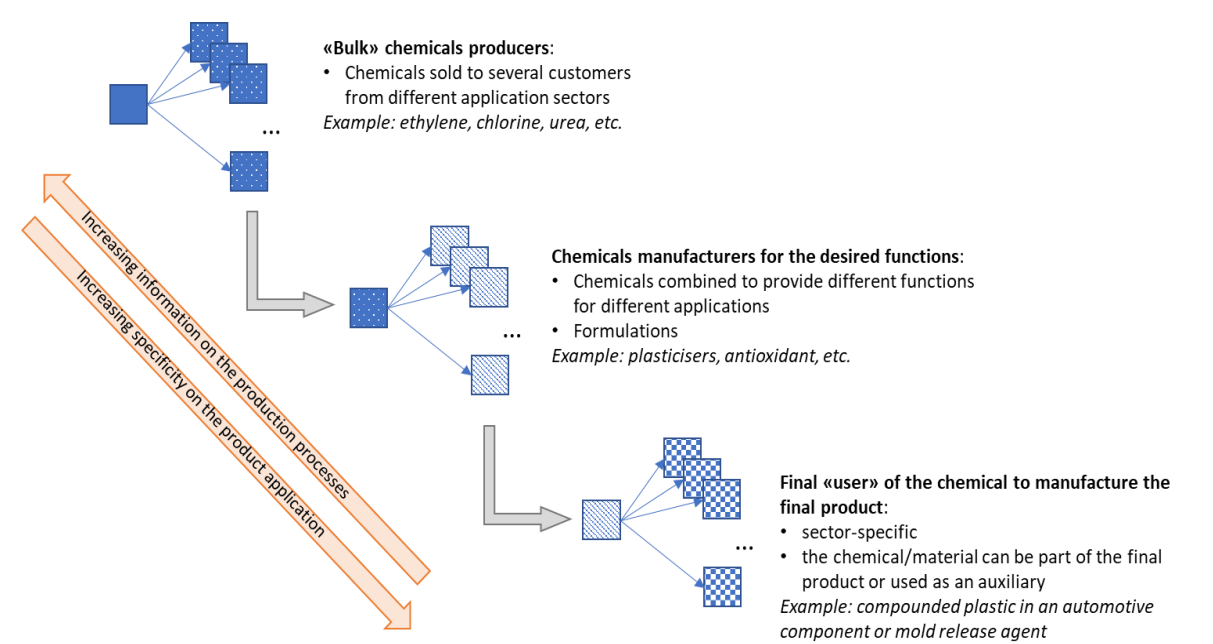
3.4. Identification and engagement with actors along the life cycle

The inclusion of a life cycle perspective highlights the importance of the value chain, making it clear that the application of the SSbD framework goes beyond the responsibility of a single stakeholder. Instead, it ideally envisages the involvement and collaboration of all stakeholders along the value chain. All the actors involved in the life cycle of a chemical/material should have an active role and a responsibility in ensuring that the chemical(s)/material(s), process(es), and product(s) are safe, sustainable, and functional (Figure 7).

However, it has been recognised that the identification of all stakeholders involved is one of the biggest challenges in the implementation of the SSbD framework, as is obtaining their active involvement, transparent collaboration, and mutual exchange of information. In the SSbD assessment, it is firstly **important to identify all the actors involved in the life cycle** of the chemical/material assessed, starting from the raw materials and until the end-of-life stage. The scoping analysis and definition of the SSbD system will subsequently clarify the position of one's own organisation

and that of the others, thus assisting the identification of key actors/stakeholders in the value chain and engaging with them early in the R&I process.

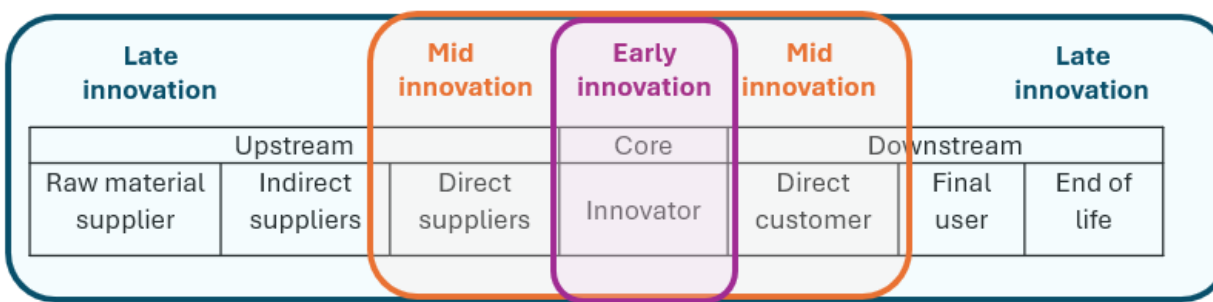
Figure 7. Conceptual example of a simplified supply chain of a chemical/material, including the number of actors involved and the possible required data and information flows.



Source: JRC

Together with the definition the system under study, and description of the intended innovation and relevant aspects, the scoping analysis supports the identification of relevant actors in the implementation of the SSbD framework. **At early stages** of innovation, when uncertainty is high, the SSbD implementation might be focused completely on the intended innovation and involve internal R&D experts. **As the innovation progresses**, engagement will involve life cycle actors close in the value chain, then potentially business to business (B2B) and business to customer (B2C) engagement will be created. **At later stages** of innovation, ideally and as far as possible, all life cycle actors should engage and contribute to the implementation of the SSbD (e.g. consortia) (Figure 8).

Figure 8. Simplified illustration of the potential progress of stakeholders’ engagement along the life cycle as the innovation progresses



Source: JRC

Engagement with life-cycle actors is essential to ensure that the SSbD system definition and choices made throughout the innovation reflect real-world conditions. Each actor contributes specific knowledge, data, and perspectives that influence safety, sustainability, and functionality outcomes.

Early engagement reduces the risk of overlooking critical aspects such as downstream exposure or end-of-life constraints. Engagement also supports the establishment of a shared understanding of decision criteria and helps to align expectations across the value chain. The level and intensity of engagement may increase as innovation progresses. It can be informal in early stages and become more structured over time.

The identification of all the actors/stakeholders in the value chain will also help to identify the roles and responsibilities in the context of safety, sustainability, and functionality performance in the value chain. Furthermore, a shared effort in meeting the ultimate goal of SSbD would represent a strong advantage, regarding possible future requirements (for safety and/ or sustainability) when placing the chemical/material on the market.

The practitioner should identify and engage **relevant life-cycle actors**, internal actors (R&D, EHS, product design) and external actors (suppliers, processors, downstream users). Engagement should ideally aim to validate the system definition, also to validate and improve the realism of any assumptions made, give access to missing data, align expectations and decision criteria and agree on trade-offs. The level and intensity of engagement may increase as innovation progresses.

Example of supply chain considerations and collaborative efforts:

- Consultation with suppliers to understand variability in raw material inputs (e.g. different types of raw materials, different sources); following on from this, the suppliers agree to provide information on raw material variability and potential countries of origin.
- Collaboration with downstream users to refine functional and exposure assumptions. Result: downstream users agree to provide information on realistic use concentrations, influencing exposure assumptions and functional indicators.
- Engagement with waste handlers to anticipate end-of-life challenges. Resulting in waste management actors refining the SSbD insights on end-of-life assumptions, additional information on the technologies used, possibilities, hurdles and feasible potential changes that might influence the efficiency of recycling, reuse, etc.

The information exchange will, at least in part, rely on the creation of a **trusted environment** for communication and collaboration among actors in the value chain (Figure 9).

One of the instruments used for these purposes are Non-Disclosure Agreements (NDAs) (e.g. GOV.UK, 2026). An NDA is a legally binding contract that establishes a confidential relationship between two or more parties. It can be either unilateral, where one party holds sensitive information and the other party receives that sensitive information. There are also bilateral NDAs, where both parties hold and receive sensitive information. Thirdly, there are multilateral NDAs. Depending on the length, complexity and additional factors, stakeholders can decide which NDA better suits their specific case.

Other points that might require consideration are business confidentiality and intellectual property rights (IPR) related to data. Some of the data or information needed for the assessment of the safety, sustainability, or functionality performance might be considered by stakeholders in the value

chain as Confidential Business Information (CBI). Both IPR and CBI are valuable assets that need to be protected and respected.

Should the use of CBI data or IPR-protected tools be needed by other actors in the value chain, the most common practice is to grant access to this protected data, or these tools, in the format of a “licence to use”, granting legitimate possession of the data or “letter of access”, granting the right to refer to the data for specific purposes e.g. SSbD.

Another important aspect to take into consideration is how these data and information might be shared in a way that it is findable, accessible, interoperable, and reproducible (‘FAIR’) by all value chain actors and sharing it in a secure and encrypted way such as via blockchain means. Figure 9 shows a possible connection of the actions described.

Figure 9. Actions to be considered during the SSbD implementation to identify and create a trusted environment among value chain actors



Source: JRC

The implementation of the SSbD framework would be only partial and limited where the practitioners had only had little interaction with other actors in the value chain. In such situations, the implementation would be based only on data available to the practitioners, e.g. via non-case-specific databases, or company sustainability reports in the case of some socio-economic indicators, with the consequent need for more assumptions and the risk of greater uncertainties or gaps.

3.5. Identification of the SSbD scenarios in an iterative and tiered scoping analysis

An SSbD scenario represents the outcome of the scoping analysis, i.e., defining the context in which the SSbD assessment is carried out. It determines, based on the maturity of the innovation and the availability of data, the maturity of the SSbD framework implementation (i.e. fulfilment of the SSbD principles)— either as a simplified, intermediate, or full SSbD implementation.

This approach allows innovators to tailor the safety and sustainability assessments based on the degree of maturity of the innovation process being considered and related data availability. The iterative approach allows tiered assessments to progressively advance towards the necessary degree of completeness in SSbD, as innovation matures (Figure 10).

The outcome of the initial scoping analysis defines the entry point (in the first iteration) to SSbD implementation. The subsequent iterations of the scoping analysis reflect the progress in the fulfilment of the SSbD principles, and then (re)define the SSbD scenario, for the next iteration. The SSbD scenarios also:

- Align the type of innovation/ (re)design with the necessary safety, sustainability considerations that are taken into account.
- Guide the problem formulation for focused and tiered assessments.
- Provide grounds for a fit-for-purpose evaluation and the consequent inputs to the decision-making situation; and
- Clearly help to document the implementation of the framework.

Table 1. Example of SSbD Scenario building based on the intended innovation and the scoping analysis elements

Scoping analysis		Simplified	Intermediate	Full
Molecular (re)design	SSbD System Definition	System boundaries defined conceptually around the molecule, its intended function, and possible environmental compartments affected	System expanded to include synthesis routes, use context, and preliminary environmental exposure pathways	System defined across production, use, and environmental fate of the molecule, considering realistic conditions
	Intended innovation	Goal: Identify promising molecular design directions avoiding inherent safety and sustainability concerns Design actions: Conceptual structural modifications (functional groups, degradable linkages, alternative structures) Safety: Qualitative hazard alerts, conceptual persistence and exposure. Sustainability: Identification of problematic elements, biodegradability potential, raw material concerns (including Critical Raw Materials), and selection of design principles (reagents, efficiency).	Goal: Compare alternative molecular designs balancing safety and environmental performance Design actions: Optimisation of molecular structure and compatibility with greener synthesis. Safety: QSAR hazard ranking, degradation estimates, exposure scenarios. Sustainability: Selection of (priority) environmental impact categories.	Goal: Demonstrate safe and sustainable molecular design under realistic conditions. Design actions: Final molecular structure and optimised synthesis route. Safety: Experimental hazard, fate, exposure, risk perspective. Sustainability: Consideration of the entire life cycle for all the environmental and socio-economic impact categories
	Actors in the Value Chain	Internal R&D experts (chemists, toxicologists, sustainability specialists) and raw material suppliers providing information on molecular building blocks or feed-stocks.	Internal R&D experts plus raw material suppliers, intermediate manufacturers, formulators, and downstream users contributing information on performance requirements and feasibility	Ideally, full value chain involvement including raw material suppliers, chemical manufacturers, formulators, product manufacturers, downstream users, distributors, waste management/recycling operators, and regulatory/compliance experts

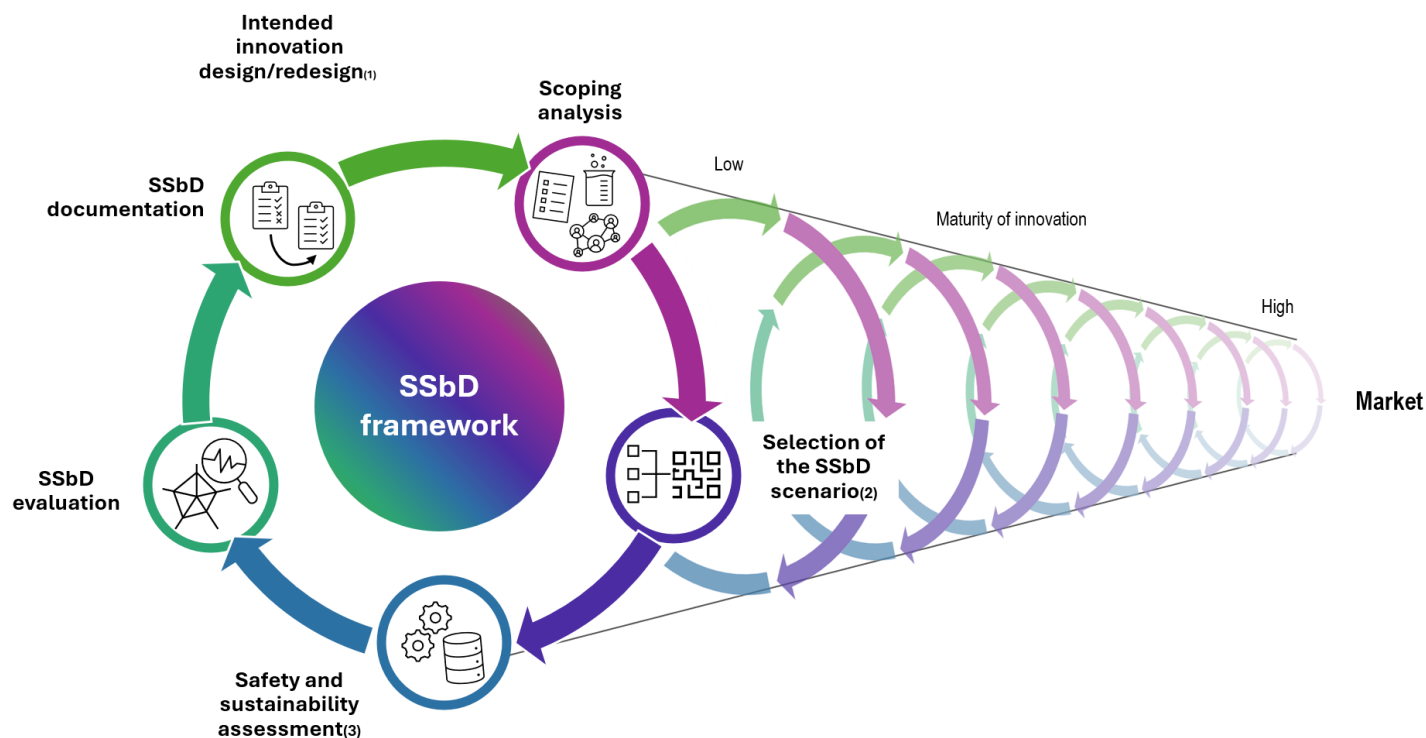
Scoping analysis		Simplified	Intermediate	Full
Process (re)design	SSbD System Definition	System defined around conceptual process steps and reaction pathways	System expanded to include unit operations and defined operating conditions	System defined at pilot scale across the full process flow
	Intended innovation	Goal: Identify safer and more sustainable process pathways Design actions: Alternative reaction routes, solvent substitution, process simplification. Safety: Conceptual hazards, accident potential, exposure pathways. Sustainability: Identification of the environmental and socio-economic hotspots in the process, and selection of design principles reflecting such hotspots such as preliminary energy, solvent, waste considerations, use of Critical Raw Materials	Goal: Compare process configurations for safety and environmental efficiency Design actions: Improve containment; optimise operational conditions; solvents/catalysts selection; reduce waste. Safety: Hazard identification, exposure scenarios, accident screening. Sustainability: selection of (priority) environmental impact categories.	Goal: Demonstrate safe and resource-efficient industrial process design in operating conditions. Design actions: Finalise process; optimise energy/material flows; implement recovery and control systems. Safety: Detailed hazard, exposure, and risk analysis. Sustainability: Consideration of the entire life cycle for all the environmental and socio-economic impact categories; assessment of supply chain vulnerability.
	Actors in the Value Chain	Internal process engineers, safety experts, and early interaction with raw material suppliers providing information on reagents and feedstocks.	Internal experts plus equipment suppliers, raw material suppliers, manufacturers, and downstream industrial users involved in pilot-scale evaluation	Ideally, full value chain involvement including raw material suppliers, plant operators, industrial manufacturers, downstream users, logistics providers, waste management operators, and regulatory/compliance experts

Scoping analysis		Simplified	Intermediate	Full
Product (re)design	SSbD System Definition	System defined around the product concept and its intended use	System expanded to include defined use scenarios and preliminary lifecycle considerations	System defined across production, use, and disposal stages
	Intended innovation	Goal: Identify safer and more sustainable product concepts Design actions: Substitute hazardous ingredients; reduce concentration; modify product form. Safety: Ingredient hazard screening; exposure potential; environmental compatibility. Sustainability: Product composition, identification of the environmental and socio-economic hot-spots along its life cycle and selection of design principles reflecting such hot-spots	Goal: Compare formulations and product designs Design actions: Reformulate; optimise delivery systems; improve packaging. Safety: Comparative hazard and exposure screening. Sustainability: Consideration of the entire life cycle for all – or a subset based on the identified hotspots – the impact categories	Goal: Demonstrate safe and sustainable product design in real use. Design actions: Finalise formulation and packaging; optimise use instructions and risk mitigation. Safety: Hazard, exposure, and risk fully characterised. Sustainability: Consideration of the entire life cycle for all the impact categories including socio-economic aspects, covering both fairness and competitiveness aspects, assessment of supply chain vulnerabilities and societal costs.
	Actors in the Value Chain	Internal product developers, formulation scientists, safety experts, together with raw material suppliers providing ingredient information.	Internal experts plus ingredient suppliers, formulators, packaging suppliers, product manufacturers, and downstream users providing feedback on performance and usability	Ideally, full value chain engagement including raw material suppliers, formulators, manufacturers, packaging suppliers, distributors, retailers, downstream users, waste management/recycling operators, and regulatory/compliance experts

Source: JRC

Figure 10. Iterative and tiered nature of the SSbD framework implementation throughout the innovation process for chemicals and materials.

The iterative approach involves repeating the SSbD framework full process, including the scoping analysis and identification of the SSbD scenario, several times during the innovation cycle. The tiered approach involves the progression through different levels or stages of innovation and refers to the level of depth and complexity in the assessment process.



(1) Innovations can be triggered for example by the need of improving existing portfolios, new market/consumer requests, new ambitions and priorities and/or policy priorities

(2) Key moment where the tailored safety and sustainability assessment is defined according to the outcomes of the scoping analysis

(3) The safety and sustainability assessment are tailored based on the selected SSbD scenario

Source: JRC

3.6. FAQs on the scoping analysis

When do I apply the SSbD?

The aim of SSbD is to guide innovation from the (re)design, along all the innovation stages, scaling up from first stages of innovation to market readiness of innovative solutions. SSbD can be applied to any type of innovation (brand new and disruptive or incremental improvement) and at any stage of the innovation.

Why do I need to carry out a scoping analysis?

The scoping analysis contextualises the intended innovation within the SSbD. It supports the identification of relevant aspects that need to be assessed in each of the innovation stages to ensure safety and sustainability and it guides the intended innovation towards the progressive fulfilment of the SSbD principles.

What is the difference between the outcome of the scoping analysis and the SSbD scenarios?

‘Scenario’ is used in the SSbD to signify the outcome from the scoping analysis. The SSbD scenario(s) represent the specific and real set of conditions (based on the scoping analysis elements) that define the context in which the SSbD assessment will be carried out. They provide a roadmap for the assessment and the evaluation of the assessment results.

What are the SSbD principles?

The SSbD principles are the fundamental pillar on which the framework is built upon:

(1) Safety and sustainability aspects are addressed with a holistic perspective throughout the entire innovation process (from (re)design to market readiness).

(2) This holistic perspective considers the entire SSbD system, including chemicals,

materials, processes, and products and their related life cycles according to the intended innovation.

(3) The SSbD concept builds on multidisciplinary engagement of the life cycle actors and company experts.

(4) transparency on the fulfilment of the principles throughout the entire innovation and traceability of the assessment is ensured.

The simplified, intermediate and full SSbD represent the degree of completeness of the SSbD principles.

What is the difference between the SSbD principles and the design principles?

The SSbD principles (explained above in the previous question) function as a governance backbone for innovation, a decision-making architecture, and an iterative assessment logic integrating safety, sustainability, and functionality across the SSbD system. By contrast, design principles (e.g. green chemistry and green engineering) are primarily technical design heuristics for improving products and processes.

What does the SSbD system represent and what does it cover?

It represents the skeleton of the system under assessment, including chemicals, materials, processes, and products and their connected life cycles according to the intended innovation.

In SSbD, substances, mixtures, materials, processes and products are linked in a value chain. Therefore, one or more chemicals and/or materials’ life cycles might be considered in the SSbD system.

4. Safety Assessment

AIM OF THE SECTION:

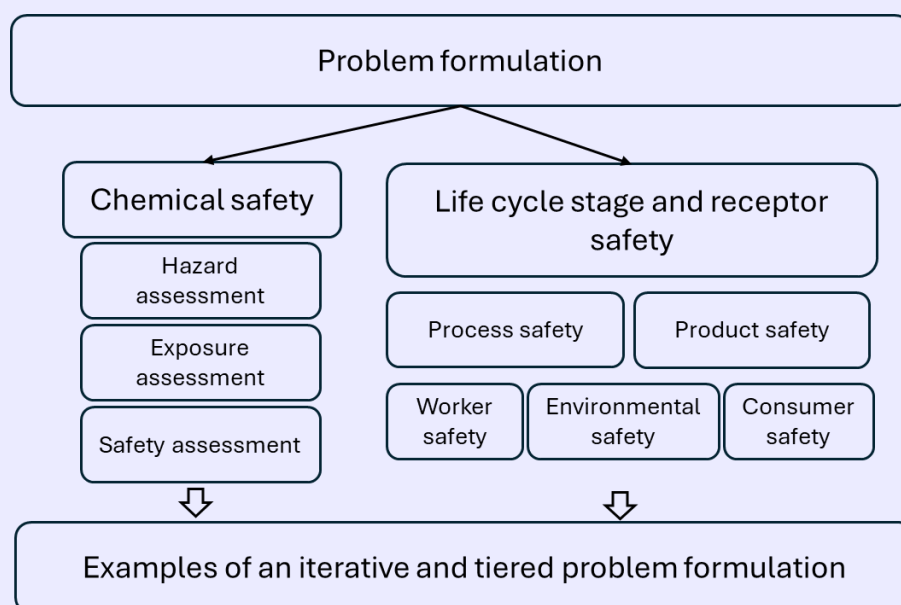
This section provides information to support the SSbD practitioner in identifying the best approach for the safety assessment in an iterative and tiered manner, as information becomes available and as the information quality and certainty increase. This section builds on and complements the holistic perspective in the scoping analysis. It zooms in into chemicals, life cycle stages and specific population safety. It provides guidance for a focused and comprehensive assessment following a source-pathway-receptor approach.

The section briefly covers:

1. Short introduction to SSbD holistic safety assessment
2. Problem formulation
3. Chemical safety
 - Hazard assessment
 - Hazard identification: the approach for collection and generation of data for the hazard classification and
 - Hazard characterisation: the derivation of maximum exposure limits.
 - Exposure assessment
 - Exposure identification and assessment
 - Safety assessment
 - Risk characterisation
4. Safety assessment from Life cycle and/or receptor perspective
5. Examples of the iterative and tiered, molecular, process and product (re)design problem formulation

Annex B. provides additional information on data sources, models, tools and checklist to support the safety assessment.

Figure 11. Structure of the safety assessment section



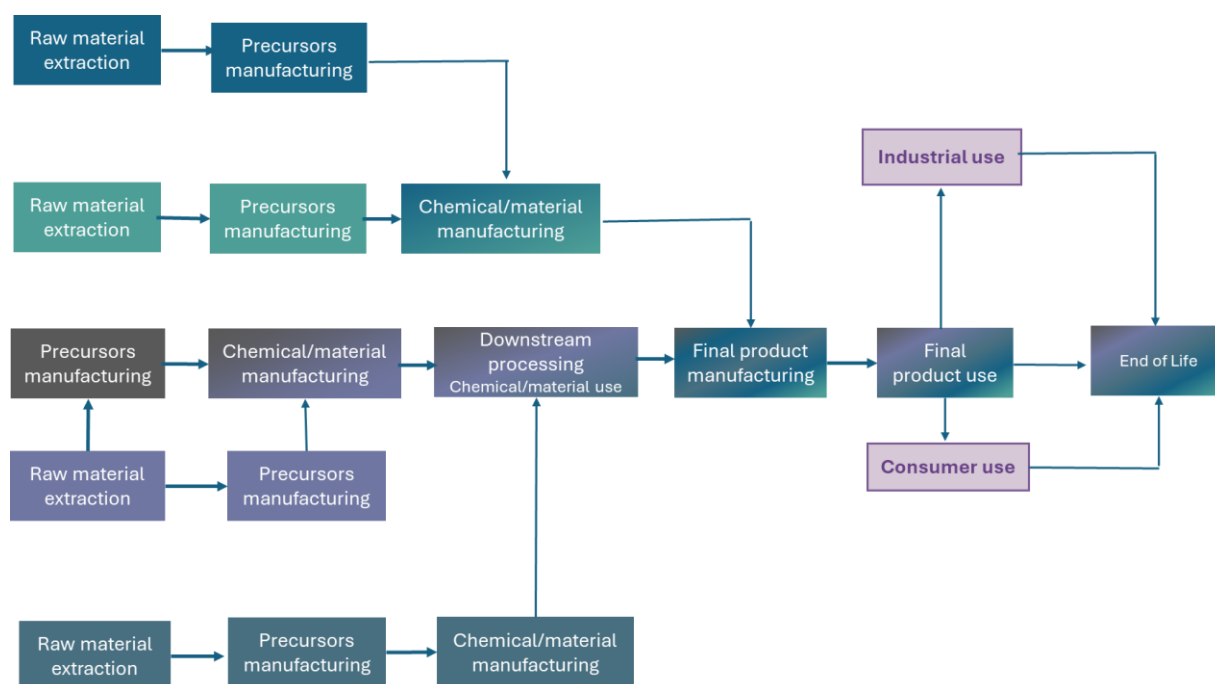
Source: JRC

4.1. Holistic safety assessment

Safety assessment is the process by which the potential risks posed by chemicals and materials to human health and the environment throughout their life cycle are systematically evaluated and managed. The process seeks to ensure that chemicals and materials can be developed, used, and managed at end of life in a safe manner. When performing a safety assessment in the context of SSbD several aspects need to be taken into consideration:

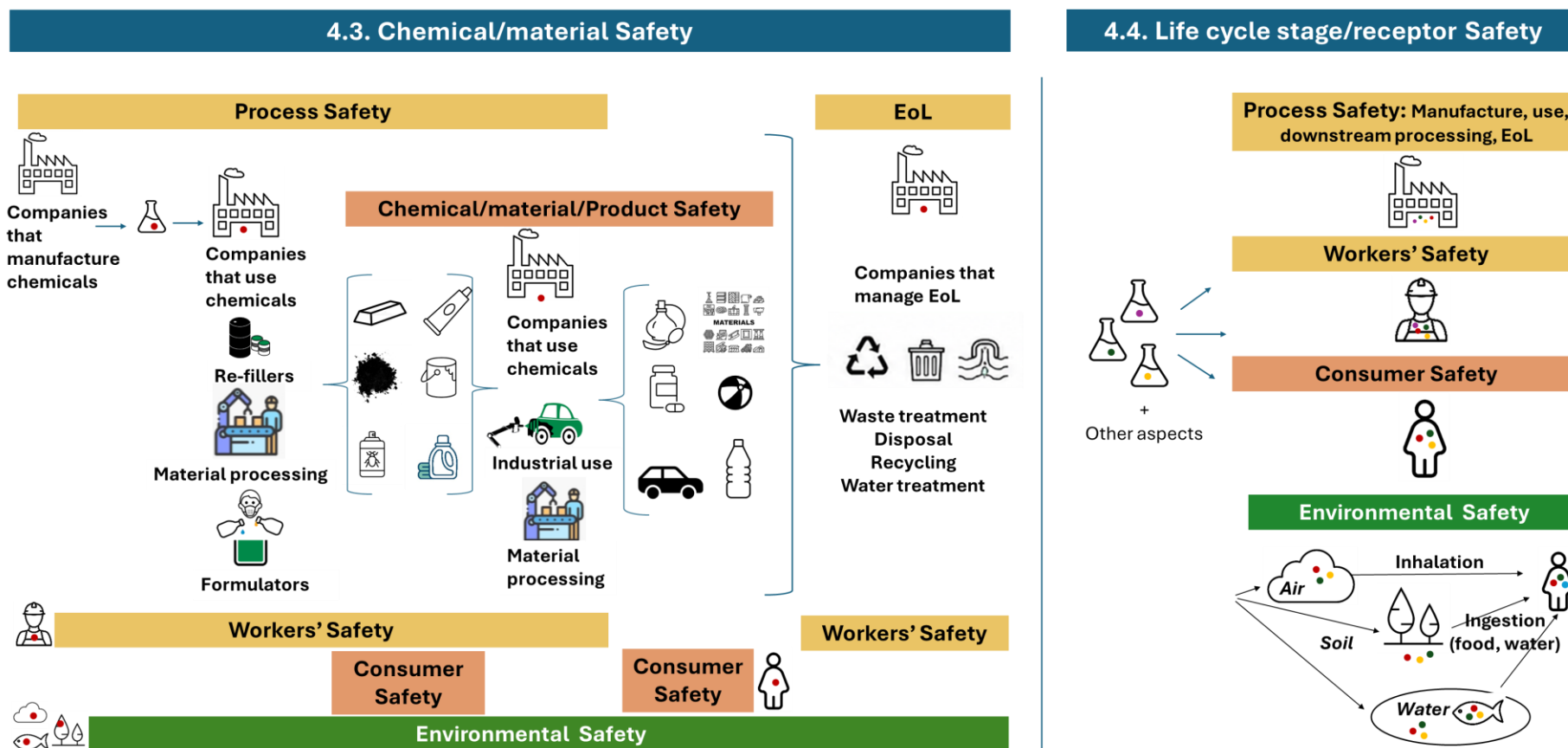
- (i) **The SSbD system under study:** In SSbD, substances, mixtures, materials, and products are linked in a value chain. Substances are the basic chemical entity that can be combined to form mixtures or transformed into materials with specific structures and functions. These mixtures and materials are then incorporated into products, which deliver the final service to users. Therefore, **one or more chemical/material life cycles might be considered in the SSbD system** definition that considers chemicals, materials, processes and products (Figure 12). Raw materials (feedstocks), reagents/reactants and auxiliaries are chemicals and/or materials framing the SSbD system (Garmendia Aguirre et al., 2026b).

Figure 12. Example of a value chain where different chemicals, materials, processes and product/applications are connected to create the SSbD System. Potential hazards and exposure can occur at every stage of the SSbD system. Running safety assessment (SA) in each stage is paramount to enable risk-based informed decisions.



Source: JRC

Figure 13. Simplified illustration of the holistic safety assessment in SSbD



Source: JRC

(ii) Holistic safety: Chemical safety focuses on the identification of the hazard properties of the chemical/material and the estimation of the risks associated with the exposure along its entire life cycle, for both human and environment. Normally this includes many safety considerations associated with properties of the chemical, particular processes in which they are involved and uses of products in which they are part of (Figure 12).

Safety can also focus on specific life cycle stages, such as process safety during manufacture, formulation safety, or product safety during use. It can also be considered from the perspective of different exposed populations (workers, consumers) and/or environmental compartments (soil, water, air), including occupational safety for workers, consumer safety for product users, and environmental safety for ecosystems. The **life cycle stages and human and/or environmental receptors safety** identify and integrate other safety aspects that are not directly associated with the manufactured chemical or material, as illustrated in Figure 13.

(iii) Assessment tier: The assessment should be proportionate, to support the decision at hand.

- **Qualitative assessment:** A qualitative assessment is a rapid, screening-level evaluation designed to identify potential safety concerns and guide early design decisions. It is typically conservative and relies on expert judgement, existing knowledge, and non-testing approaches. The objective is not to provide definitive conclusions, but rather to avoid unsafe design directions at an early stage.
- **Semi-quantitative assessment:** A semi-quantitative assessment uses model-based predictions and comparative metrics to refine safety understanding. It supports comparison between design options, helps to fill data gaps, and provides a more structured estimation of hazard, exposure, or risk. This tier of assessment enables informed optimisation decisions without requiring full regulatory-level data.
- **Quantitative assessment:** A quantitative assessment is robust, comprehensive, and well-documented. It integrates hazard and exposure data to characterise risk in numerical terms and is suitable for regulatory decision-making (pre-demonstration) and for validation/demonstrating safe use in scale-up and real conditions. This tier of assessment requires higher-quality data, clearly defined scenarios, and explicit uncertainty evaluation.

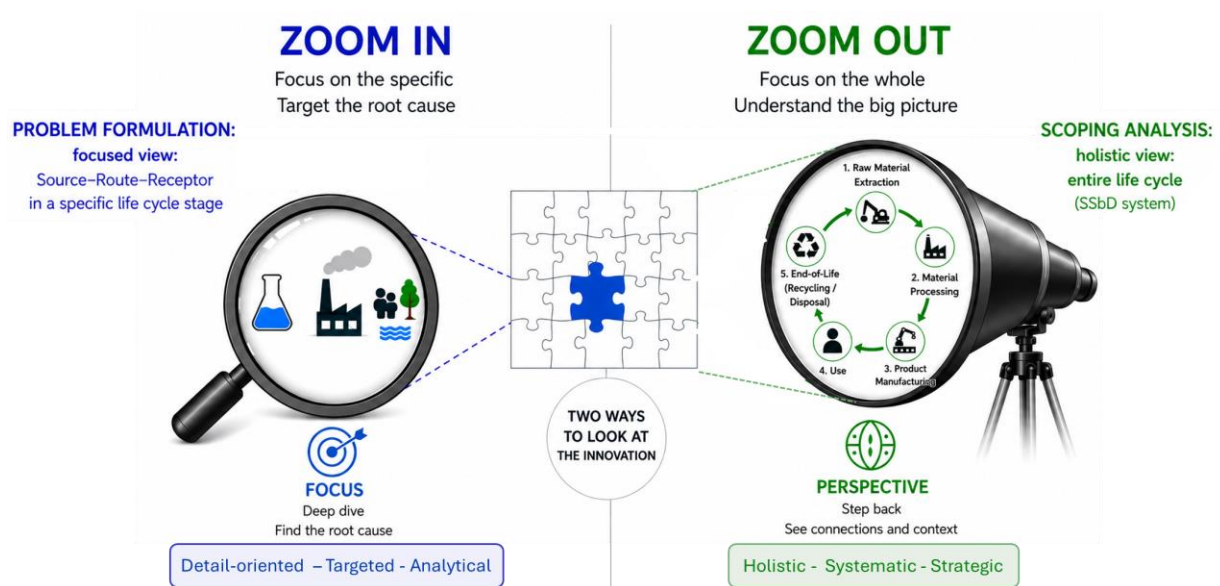
These tiers described here should not be confused with the simplified, intermediate and full SSbD that describe the level of completeness of the SSbD principles (See 3.6 FAQs on the scoping analysis FAQs on the scoping analysis).

4.2. Problem formulation

Since there is no “one-size-fits-all” approach for safety assessment, the SSbD practitioner must make several methodological choices at each step of the innovation process. These choices can lead to potentially different approaches, thus guiding innovation through different pathways and types of SSbD implementation. Therefore, for transparency and traceability purposes, documenting the different decisions taken during the innovation process is paramount.

Scoping analysis and problem formulation improve transparency and traceability by laying out assumptions, limitations, and reasoning in each iteration of the SSbD implementation and safety assessment. **While scoping analysis supports the implementation of the SSbD principles and the holistic safety considerations, problem formulation supports the targeted and focused safety assessment of the innovation** (Garmendia Aguirre et al., 2026b). (Figure 14).

Figure 14. Scoping analysis and problem formulation in SSbD safety assessment



Source: JRC

The SSbD scoping analysis establishes the overall boundaries, priorities and decision context for SSbD implementation. It is not a safety assessment, but a strategic orientation step that determines whether a focused safety assessment is needed, what it should focus on and at what level of detail. The problem formulation takes the outcomes of the scoping phase and translates them into a structured and proportionate safety assessment plan. This plan should address specific and focused safety questions, to enable a complete and robust safety assessment to be carried out.

Problem formulation is a systematic and iterative approach to define and characterise problems by understanding their critical components, and then formulating pertinent strategies to address the problem, via:

- (i) Framing the problem to provide clarity and to agree on the specificities to be addressed. A structured problem formulation enables the practitioner to focus on describing and evaluating the specifics of the problem to be solved, instead of immediately creating solutions.
- (ii) Exploring the problem, to transform it into an operational series of questions to be answered, and hypotheses to test.
- (iii) Mapping the approach to testing hypotheses and developing the analysis plan to address the problem (Sauve-Ciencewickia, 2019).

The scope and purpose defined during problem formulation determines which system elements (e.g. chemical(s)/material(s), processes or products), will be assessed which hazard, exposure and risk components are to be prioritised, which tier of assessment is appropriate, and which methods and tools are proportionate with regard to the specific SSbD iteration

The problem formulation should focus firstly on the innovation; each iteration will then complement further details to reach a comprehensive safety assessment, fulfilling the SSbD principles.

4.2.1. Elements of the problem formulation

A short description of the elements needed in problem formulation is provided below:

- (i) **Purpose and Decision Context:** Any safety assessment conducted within an SSbD framework must begin with a clear definition of its purpose and decision-making context. The assessment should explicitly state which specific safety decision it is intended to support, e.g.: Early design/ screening, Design optimisation/ comparison of alternatives, Demonstration of safe use or Regulatory support (in which case the legislation must be specified).

Clarifying the intended decision-making context determines the depth, complexity, evidence needed and the type of assessment (qualitative, semi-quantitative or quantitative). It is equally important to define the acceptable level of uncertainty for information feeding into support the decision at hand. Early-stage screening may tolerate higher uncertainty, whereas decisions related to market deployment or regulatory compliance require lower uncertainty and stronger supporting evidence.

- (ii) **Assessment Scope:** A clear definition of the scope is essential to ensure transparency and relevance. The assessment scope must specify which chemical(s), material(s) are included, and must identify the expected exposure routes during the process or in the application/ use of the product.

The assessment scope should also specify its focus, for example if the primary focus is on a specific chemical substance, the relevant hazard endpoints must be identified (e.g., acute toxicity, carcinogenicity, ecotoxicity), along with the relevant exposure routes and pathways (e.g. inhalation, dermal contact, aquatic discharge). It should define which life-cycle stages are assessed in detail (e.g. production, use, disposal) and identify the use or release scenarios that are modelled. It should also clearly define which life-cycle stages are out of scope and for which reason. In addition, the assessment scope must clarify which populations or environmental receptors, such as workers, consumers, general population, aquatic organisms, or terrestrial species, are explicitly evaluated. Defining these boundaries ensures that conclusions are interpreted within the correct system context.

- (iii) **Assessment Approach** Depending on the type of innovation (molecular, process, product), the primary safety challenge to be addressed by the innovation and the maturity of innovation itself, safety assessment may begin from different perspectives. In a molecular innovation, the assessment may initially focus on intrinsic properties as these are often unknown for the new chemical/material under development. Identifying characteristics (e.g. structural alerts) that may indicate hazardous properties such as toxicity, persistence, or bioaccumulation, may therefore be the primary focus at this stage. In a process or product innovation, the assessment may initially focus on potential new use patterns, the resulting release patterns and potential exposure of humans and environment arising from these releases. Process and product innovation may also begin by focusing on the risk for a specific receptor or exposed population (e.g. workers in process innovations or consumers in product innovations) ensuring that relevant safety thresholds are not exceeded (Table 2). **Regardless of the starting point, safety assessment is always conducted as a comprehensive assessment in which all three safety aspects are considered.**

In the safety assessment, the tiered approach results in the assessment levels being referred to as ‘qualitative, semi-quantitative and quantitative’ assessment and not as ‘simplified, intermediate and full’. However, these latter terms still refer to the completeness of the safety considerations along the SSbD system.

Table 2. Example of main elements considered based on the assessment approach

Approach	Safety assessment: focus on hazard	Safety assessment: focus on exposure	Safety assessment: focus on receptor's risk
Applicability	This approach is applied in early design with substitution purposes, assessment of new chemicals or materials or comparison of alternatives with similar uses to understand whether the intrinsic properties of a chemical or material are compatible with the set objectives.	This approach is applied in the redesign of a specific process or product stage, for identification of risk hotspots in the life cycle or improvement of specific operational/use conditions to identify and reduce exposure and risk hotspots associated with a defined life-cycle stage.	This approach is applied to ensure adequate protection of a defined receptor, even under conservative assumptions.
Assessment	The assessment follows a hazard-driven approach followed by exposure screening with emphasis on intrinsic properties independent of specific uses. And it answers questions such as: • Does the substance/material exhibit hazardous properties of concern? • Are there structural alerts that preclude safe use by design? • Are there inherent properties that are difficult to manage by exposure control?	The assessment follows an exposure-driven approach followed by risk characterisation where hazard considered only for relevant exposure pathways. And it answers questions such as: • Where and how does exposure occur at this stage? • Which process/use parameters drive exposure? • Can exposure be reduced by (changing these parameters? Process/product application (re)design?	The assessment is risk-driven, starting from exposure and effects relevant to the receptor. Other life-cycle stages are considered only if they affect the receptor. And it answers questions such as: • Is this receptor sufficiently protected under intended use? • Are there exposure pathways unique to this receptor? • Are specific endpoints (e.g. developmental toxicity) critical?
Main elements	The elements that scope the assessment are the chemical identity, composition and impurities, the material properties such as form, size and surface characteristics and generic life-cycle stages (screened, not fully modelled)	The elements that scope the assessment are the definition of the life cycle stage (e.g. formulation, use, end of life), Specific processes, operating/use conditions and controls and a limited set of populations and release pathways.	The elements that scope the assessment are: One or more defined receptors (e.g. workers, consumers, aquatic species), the relevant exposure routes and effect endpoints and the selected life-cycle stages influencing exposure.

Source: JRC

- (iv) Criteria and Decision Rules:** Criteria and decision rules can be defined to demonstrate the achievement of the (re)design goal by focusing on the relevant safety aspects at different stages of innovation and SSbD iterations. However, **at the end of the innovation process these must be defined to demonstrate overall safety in the SSbD System.** These might also evolve from qualitative to quantitative in alignment with the decision-making context

(screening, comparison between design options, optimisation, etc) and the maturity of innovation.

The SSbD practitioner should specify criteria used to judge the results (e.g. thresholds, indicators: DNEL / PNEC, RCR < 1, Hazard class absence (e.g. no CMR), Exposure band targets, or other relevant aspects and indicators). Criteria and decision rules can also use weighting strategies or prioritise aspects and indicators. How indicators, populations or life-cycle stages are prioritised and how results are interpreted (e.g. pass/fail, ranking) must be specified for a transparent decision-making. Any conditions that trigger redesign, further refinement, or rejection of a design option should be also included.

Criteria and decision rules should be transparently documented to prevent ad hoc or inconsistent decisions.

- (v) **Data Needs and Strategy:** A structured data strategy should be developed from the beginning. The data strategy should be proportionate to the decision context. The data strategy should identify which relevant data already exist and which data gaps might affect the safety assessment and subsequent conclusions. The strategy should also describe how unnecessary testing will be avoided, and prioritise read-across, modelling, and other new approach methodologies, where scientifically appropriate.

The practitioner should clearly describe which models and tools are used to address specific hazard endpoints, exposure or risk. When selecting tools for safety assessment, practitioners should ensure proportionality (tool complexity matches decision needs), transparency (assumptions and uncertainties are documented), iterative approach (assessments are revisited as designs evolve), and regulatory coherence (alignment with existing legislation and guidance).

The data strategy should specify whether the approach is deterministic or probabilistic. A deterministic approach uses single fixed input values (often worst-case or average assumptions) and produces a single outcome for hazard, exposure, or risk. This approach is simpler and is often suitable for screening or conservative assessments. A probabilistic approach uses ranges and statistical distributions to represent variability and uncertainty, producing a range of possible outcomes with associated probabilities. This approach is more data-intensive but provides deeper insights into uncertainty and variability.

Uncertainties that materially influence the outcome should be identified and documented, along with a plan for refinement in subsequent iterations, as needed.

4.2.2. Iterative and tiered problem formulation

Problem formulation and safety assessment are inherently iterative in SSbD. **Assessment results should systematically feed back into design, problem formulation and decision-making for the next iteration where safety assessment will be refined, expanded or complemented in a higher tier assessment approach.**

Tiers define the level of depth and complexity in the assessment process and represent the progressive steps in analytical detail, and the related data requirements, quality needs and degree of decision confidence. Therefore, the number of iterations and tiers for safety and sustainability assessments performed can be as many as are necessary, depending on the nature of the assessment, the type of innovation contemplated and its maturity.

Progression between tiers should be needs-driven and proportionate. Escalation to more complex or data-intensive assessments should occur when necessary to support the decision at hand. It should be noted that the tiers described for the hazard, exposure and risk driven approaches do not necessarily need to align with each other. The tiers define the level of depth and complexity in the assessment process and represent the progressive steps in analytical detail, data requirements, quality needs and decision confidence. (See section 4.5. for examples of iterative and tiered problem formulation).

4.3. Chemical safety

Chemical safety assessment is the process by which the potential risks posed by chemicals and materials to human health and the environment throughout their life cycle are systematically evaluated. The process seeks to ensure that chemical and materials can be developed, used, and managed in a safe manner.

Box 3. Chemical/material identification and characterisation

Chemical and material identification and characterisation is key to the assessment, to ensure that what is being assessed (the source) is well defined and understood. Substance identification provides the information needed to uniquely define and distinguish the substance from others, such as its chemical name, molecular structure, CAS number, molecular formula, composition, and identity of constituents, impurities, or additives.

This then enables appropriate modelling and testing to be performed and give transparent support to decision-making throughout the safety assessment process. Without a robust characterisation, any subsequent hazard, exposure, or risk assessment may be unreliable or misleading (ECHA, 2023). Chemical and material characterisation also describes the combination of physical and chemical characteristics, such particle size distribution, morphology, surface properties, purity profile, stability, solubility, dissolution behaviour, and other attributes that influence, e.g., (eco)toxicological properties and how these behave under different use conditions. The composition of the source is also important to describe, i.e., is it a mono constituent, multi-constituent or a substance of unknown or variable composition, complex reaction products or biological material (UVCB) and its impurities. All this information will influence the safety assessment and its robustness, starting from the identification of the available data and applicable tools. For complex materials and mixtures, characterization may also include information on variability, fractions, and functional properties. This then enables appropriate modelling and testing to be performed and give transparent support to decision-making throughout the safety assessment process. Without a robust characterisation, any subsequent hazard, exposure, or risk assessment may be unreliable or misleading (ECHA, 2023).

The key aspects of chemical safety assessment are the hazard assessment (identification of the intrinsic properties and their adverse effects on biological systems), the exposure assessment (identification of the use and the prediction of exposure to human and environmental receptors) and the risk characterisation (the estimation of the likelihood and severity of the effects). These aspects are considered throughout the life cycle of the chemical/material, including manufacturing, formulation or re-packing, end-use (article) service life and end of life (e.g. waste management). These aspects are also considered for all receptors including workers, professionals, consumers and environmental compartments and general population (human exposure via the environment). The safety assessment follows the “source-pathway-receptor” approach, meaning that the process needs to be repeated as many times as there are possible combinations of these three elements.

The approach for tailoring the assessment is based on whether the focus is on a specific chemical or material, a specific life-cycle stage, or a specific receptor including a target population. The

assessment may have a stronger focus on the hazard, exposure or risk. **It is however important to emphasise here again that safety assessment should always consider all three aspects: hazard assessment, exposure assessment, and risk characterisation.**

4.3.1. Hazard assessment

The process comprises three elements: (1) data gathering, generation, integration and evaluation for hazard identification (Figure 15), (2) hazard classification and (3) derivation of the hazard thresholds for the specific assessment target (Figure 16). These elements are further explained in the following subsections.

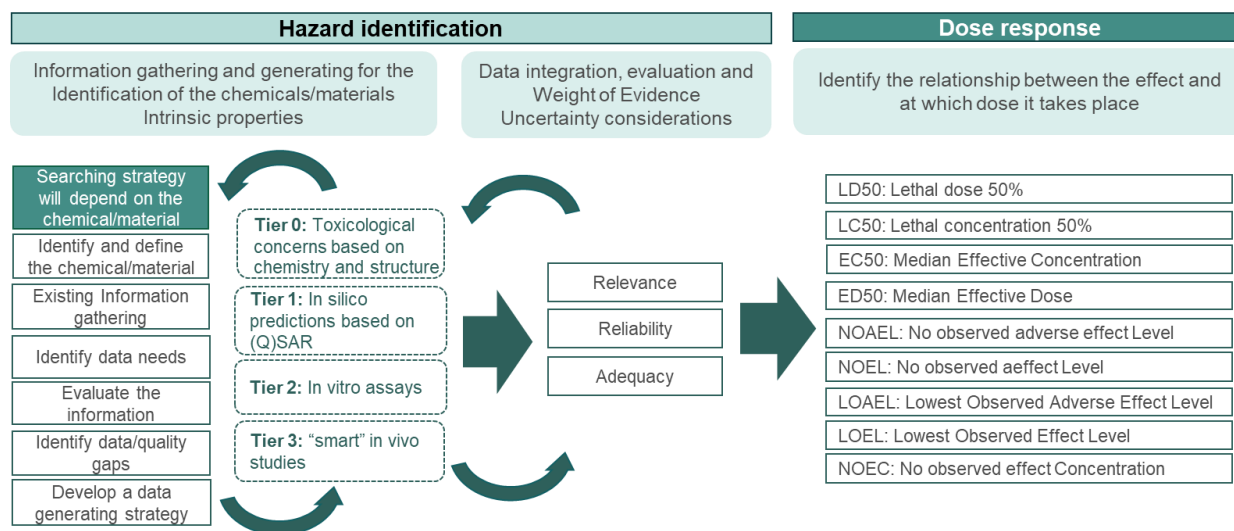
4.3.1.1. Hazard identification: Data gathering, generating, integration and evaluation

The hazard assessment starts with the hazard identification by gathering all relevant available physicochemical, toxicological and ecotoxicological information (Figure 15).

It should ideally consider the steps described here under:

- i. Identify and define the chemical(s)/material(s) under assessment
- ii. Based on the problem formulation, the SSbD practitioner should identify the data needs, e.g. quality (incl. uncertainty) and completeness, to give answer to the formulated problem.
- iii. Practitioners should gather all available and relevant data with regards to the physico-chemical, toxicological and ecotoxicological properties according to the identified needs.
- iv. Evaluate the reliability, relevance, and adequacy of the available information for arriving at hazard conclusion.

Figure 15. Scheme of the relevant aspects for the hazard identification



Source: JRC

The innovator should collect all available information, which can include:

- Information about the chemical/material identity
- Physicochemical data
- Non-testing data: i.e. data obtained with (Q)SAR models, grouping, read-across, weight of evidence etc.
- Testing data: including all in vitro and in vivo testing data, as available
- Human data, including epidemiological data, where available
- Any other data that may assist in identifying the presence or absence of hazardous properties

This information might be gathered from various sources:

- Internal sources available to practitioner(s)/innovator(s)/trade association(s)/etc.
- Regulatory and scientific databases
- Scientific peer-reviewed literature and grey publications
- Internet searches
- Textbooks
- New Approach Methodologies (NAMs).

A first hazard identification issue for chemicals/materials is the amount of data needed in relation to their intrinsic properties, to draw initial conclusions on their classification according to the CLP criteria (EU, 2008a). According to REACH (EU, 2006a), existing chemicals and materials must have certain data when placed on the market in quantities above one tonne per manufacturer/imported per year. However, for new chemicals and materials at low tonnages, the available data may be quite limited. Other legislation, e.g. the Biocidal Products Regulation, also have data requirements, but no tonnage triggers. Depending on relevance, the substance under scrutiny may already be classified based on that data.

The search strategy will depend on the chemical/material nature, its specificities, and the problem formulation (see above). Whichever strategy has been followed, it is important to record which assumptions have been made and why, what has been done following these assumptions and what has been the outcome.

If available data is not sufficient to draw conclusions in line with the problem formulation, the practitioner should then identify data and quality gaps according to the data needs and the problem formulation; then a data generation strategy is needed to fill in these gaps.

The process of gathering data is an iterative process that leads to a collection of progressively more refined and higher quality data over time.

- In Tier 0, hazards are identified based on existing literature to define the scope of the assessment, determine the endpoints of interest, and gather all accessible existing information.
- In Tier 1, this information should be completed by looking for additional data and higher certainty levels; computational models are used to predict hazard, based on chemical structure and similarity to known substances (e.g. (Q)SAR).
- In Tier 2, this information is complemented with data from in vitro assays that are mapped onto Adverse Outcome Pathways (AOPs) to predict potential in vivo effects. AOPs are

models that describe sequential chain of causally linked event at different level of biological organisms that lead to an adverse effect in the human health or environment (OECD, 2026a).

- In Tier 3, and where Tier 0–2 data are insufficient for regulatory decision-making or key uncertainties remain, confirmation via smart *in vivo* testing exist (e.g. Intelligent Testing Strategies) . integrated approaches to testing and assessment (IATAs) might be needed.

At the beginning of innovation, the practitioner might prioritise the availability of data regardless of its quality and the associated degree of certainty to have an early indication of “red flags” (raising awareness of a potential hazard) Box 4. Alternatively, s/he might prioritise instead the quality and certainty of data for a specific endpoint that raises a (potential) concern during the use of the chemical/material.

Box 4. Use of QSARs at early innovation stages

At the early stages of new molecular innovation, data is very scarce and new approach methodologies (NAMs) data, such as from *in vitro* tests, and *in silico* models and tools (e.g. quantitative structure–activity relationship models (QSARs)) are relevant means to support and guide the innovation process towards non-hazardous chemicals and materials, since they provide information that is relatively economical to obtain.

However, as in other methods used for data generation and evaluation, NAMs also have their limitations. NAMs need to be used and considered by experts, and utilised in conjunction with expert judgment, to draw appropriate conclusions from the provided results. Another aspect which needs to be considered is that *in silico* tools usually build their prediction models based on pure chemical substances. Therefore, they may not be applicable to industrial substances or materials which can contain impurities or mixtures, which may not be well identified. The impact of impurities needs to be evaluated on a case-by-case basis. Mixture effects could, in principle, be assessed using principles of additivity, assuming that the mixture composition is well known, though the assessment must also recognise potential synergistic and antagonistic effects. In the case of advanced material tools and methodologies have been adapted and developed to address these needs (Pomar-Portillo et al., 2025).

Nevertheless, at the early innovation stages, there is a need to easily and reliably predict data to identify “red flags” as early as possible. As mixtures and materials are composed of substances, one way to identify these red flags is to choose the “substance/ component approach”. In this way, specifically at early innovation stages, the innovator/ practitioner may perform the assessment on individual components (substances) of a mixture or a material to address the data needs, using *in silico* tools.

At the end of the process the practitioner should be able to derive the dose-response parameters relevant for the hazard classification (See 4.3.1.2.) and characterisation (4.3.1.3)

The data gathering strategy will therefore depend on the chemical/ material specificities and the problem formulation.

Literature and methodologies are more frequently available and applicable to pure organic substances and/or existing chemicals, compared to the information available for new or more complex substances or advanced materials. Therefore, the SSbD practitioner should take into consideration these limitations in early stages of molecular (re)design where new substances, mixtures, UVCBs or advanced materials are assessed. Whichever strategy and adaptations have been followed, it is important to record which assumptions have been made and the associated level of uncertainty for the purpose of feeding into the subsequent decision-making.

4.3.1.2. Hazard classification

Criteria for the classification, labelling and packaging (CLP) of substances and mixtures (EU, 2008a) build on (eco)toxicological data and the following dose-response descriptors obtained in the hazard identification such as Lethal Concentration 50% (LC50), Lethal Dose 50% (LD50), No Observed Adverse Effect Level (NOAEL), No Observed Adverse Effect Concentration (NOAEC), etc (Figure 15).

In the EU, chemicals classified under CLP are subject to strict controls to protect human health and the environment. For example, substances identified as CMRs (carcinogenic, mutagenic, or toxic for reproduction) or EDs (endocrine disruptors) are prioritised for regulatory action under frameworks such as REACH. These substances may be placed on the Candidate List of Substances of Very High Concern (SVHCs), which can potentially lead to authorisation requirements or restrictions on use.

SSbD aims to complement, or pre-empt, these reactive measures by setting preventive hazard criteria in innovation. These criteria should be understood with respect to the full ambition of the SSbD, i.e., to support the development of new solutions that do not present either safety or sustainability concerns and supporting innovation towards continuous safety (and sustainability) improvement of existing solutions.

In this sense, **the SSbD framework proposes a hazard-based criteria** that build on the CLP criteria, where CLP hazard classes and categories are split into three groups: most harmful substances (H1), Substances of concern (H2) and other hazard classes (H3) (Caldeira et al., 2022a). The purpose is to function as an **early warning system** (with the purpose of providing red flags) and to raise awareness on certain hazard aspects (structural alerts, CLP classification when available, etc) that the innovator should consider, as well as preventing or anticipating future consequences and legal requirements (bans, restrictions, limitations in use, etc.), (see Table 5 of the revised SSbD framework, Garmendia Aguirre et al., 2025a).

4.3.1.3. Hazard characterisation

From the (eco)toxicological data information, collected, generated, and evaluated and the related dose-response descriptors, the practitioner can derive the tolerable maximum level of exposure for the safety assessment. These tolerable maximum levels are derived from the hazard endpoint by applying assessment factors that quantify the effect of the chemical on a certain population (Figure 16).

The tolerable maximum levels are the levels above which a particular human population (e.g. workers, consumers) or environmental compartments (soil, water, air) should not be exposed. These levels are the reference values for: the specific chemical and hazard endpoint, exposure route and effect and receptor (human population and environmental compartment) (Table 3).

Table 3. Overview of exposure patterns for human population and environment

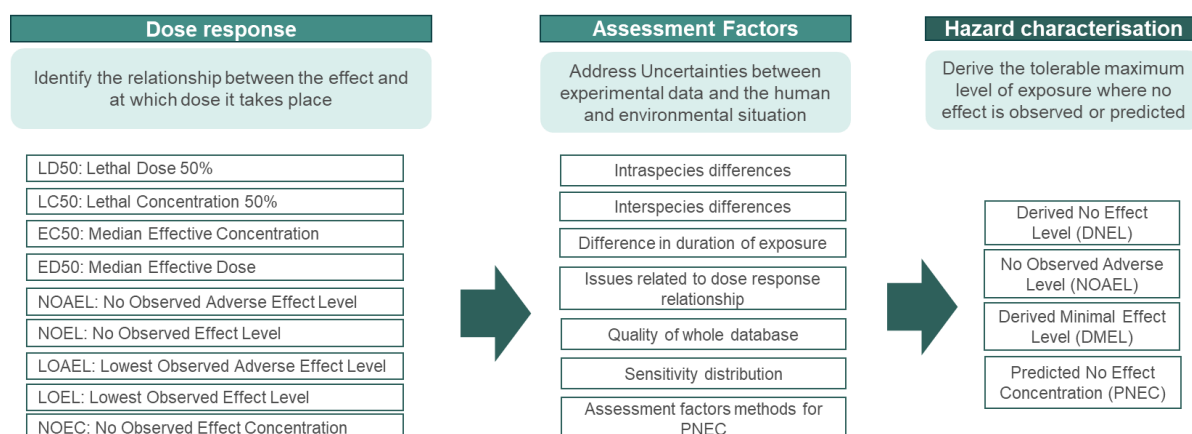
Human health			Environment	
Population	Effect		Compartment	
Workers	Acute	dermal, local effects	Aquatic compartment	Fresh Water
		inhalation, local effects		Marine Water
		inhalation, systemic effects	Sediment	Fresh water sediment
	Long term	dermal, systemic effects		Marine sediment
		inhalation, systemic effects	Terrestrial (Soil) compartment	
		dermal, local effects		
Consumers/General Public	Acute	inhalation, local effects	Sewage treatment plant micro-organisms	
		inhalation, systemic effects		
		dermal, local effects	Air compartment	Biotic
	Long term	dermal, systemic effects		Abiotic
		inhalation, systemic effects	Predator	Fish eating predators
		oral, systemic effects		Worm eating predators
		dermal, local effects	Man via environment	Inhalation
		inhalation, local effects		Ingestion

Source: Table 8 of the SSbD Framework (Garmendia Aguirre et al., 2025a).)

Safety uncertainty factors or assessment factors are used to derive a reference dose that is considered safe, or below which an adverse effect is unlikely to occur. These factors are used to address the differences between experimental data and the human and environmental situation, considering the uncertainties in the extrapolation procedure and in the available data set (ECHA, 2012a). The value of the factor depends on the toxic effect, the size and type of the population to be protected and the quality of the (eco)toxicological and exposure data available (EFSA, 2026).

The exposure levels predicted or measured based on the use/exposure scenarios (see section 4.3.2), are compared against these tolerable exposure values (DNEL, NOAEL, DMEL, PNEC, OELD, TDI) to characterise the risk, as shown in Figure 16. (For more information See section 10.2. Safety assessment in innovation of the SSbD revised framework).

Figure 16. Scheme of the relevant aspects for hazard characterisation



Source: JRC

4.3.2. Exposure assessment

Understanding and estimating the exposure to a chemical/ material is one of the fundamental requirements for safety assessment. The assessment start with the **identification of the use case** (see Annex B.2.). The use case explains how actors in the value chain interact with the chemical/ material in its life cycle (the SSbD system). **The use case describes scenarios that could raise concern(s) with regard to the safety to human health and /or the environment (exposure scenarios).** This is of paramount importance in safety assessment, because although the intrinsic properties of the chemical/material (hazard) remain the same during the entire life cycle, the exposure and therefore the risk will be specific to the use case.

Relevant aspects for the exposure identification and assessment as described in this section are shown in Figure 17. The description of the use(s) is based on multiple elements, including the definition of the scenarios in which the exposure occurs, the technical functionality and the products that are placed on the market from the use in different value chains.

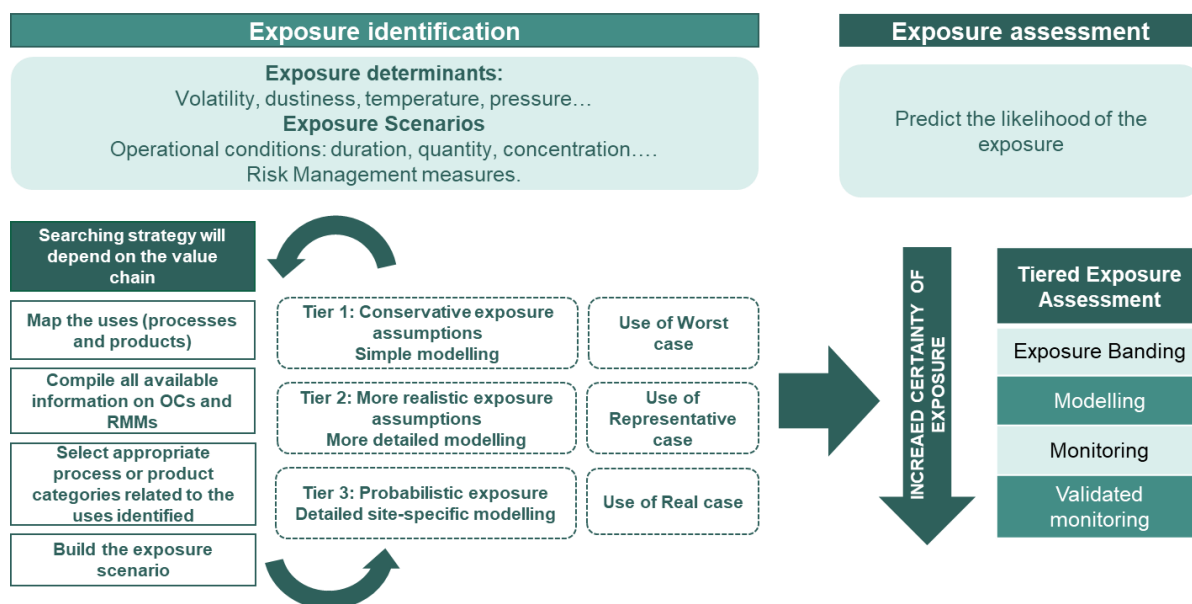
Activities that need to be considered start with the first actor in the life cycle of a chemical/ material, i.e., the manufacturer/ producer of the chemical/ material, and include processes by which the chemical/ material is produced from raw materials. This is followed by processing activities such as formulation, where relevant, and/or other activities undertaken by workers to produce other chemicals and materials, processing of semi-finished products, etc. Subsequently, there are those activities that are performed to produce the final product (e.g. via calendering, spraying, extrusion).

In these activities the chemical/ material might be consumed during the reaction(s)/process(es) and transformed into another chemical/ material such as raw materials or precursors; the chemical/ material can intentionally be added as a component in a mixture/ formulation process; the chemical/material may be used in the manufacturing process but is not meant to be part of the final product, then it is referred to under the category of “auxiliary” chemical; or the chemical/material can also be used in the manufacturing of a product, where it is meant to be a part of it.

How the final product is used is also part of describing the use case. Therefore, such information as the description of the product, how it is applied, in which sector and by which end users is also needed for completeness of the use case. Finally, there will also be activities undertaken related to the end-of-life stage (e.g. waste disposal, waste management, treatment or recovery). In all these activities the function of the chemical/ material needs to be understood.

Figure 17 also shows how **exposure scenarios** describe the **operational/use conditions and how risk management measures are applied** to ensure that these uses are deemed safe (i.e., the risk to human health and the environment is considered to be under control) during the life cycle of the chemical/material. Exposure scenarios may include several contributing scenarios that describe each contributing activity within an identified use. Examples include mixing, sampling, cleaning and maintenance activities, transferring into small containers, or applying a substance or mixture by spraying.

Figure 17. Scheme of the relevant aspects for the exposure identification and assessment. OC: Operational Condition, RMM: Risk Management Measure



Source: JRC

The development of the relevant exposure scenarios starts with mapping the processes and products in which the chemical/ material is used. The SSbD practitioner should consider all potential uses of the chemical/ material beyond the immediate actor(s) in the supply chain. Standard use descriptors might be used, as appropriate (ECHA, 2015; OECD, 2025a; US EPA, 2026a; Isaacs et al., 2020) to define the uses according to e.g. life cycle stage, sector(s) of use, product type, article type, process category, or their technical function. (See Annex B. 2.).

Besides describing the use, the conditions in which these uses take place need to be considered for the exposure estimation. SSbD practitioners should compile all available information on Operational Conditions (OCs) and Risk Management Measures (RMMs) related to these uses during the life cycle (Table 4).

Table 4. Generic Operational Conditions and Risk Management Measures

Operational conditions	Risk Management/Mitigation Measures
Amount (i.e. percentage (w/w)) of chemical/material in the process or product	Containment of the process/Use
Physical form	Room ventilation
Duration and frequency of the exposure (processing or use)	Local exhaust ventilation
Place of use. The environment in which the exposure takes place	Personal protective Equipment: Respiratory protection, dermal protection, face and eye protection
Operating/use temperature	Best Available Techniques
	Instructions/communication of safe use for consumers

Source: Garmendia Aguirre et al., 2025a

The identification of the exposure scenarios, including the description of the operational conditions/use conditions, provide the information necessary to predict the exposure potential. This may then be minimised, to ensure safe use via applying risk management measures.

The ECHA guidance on [Risk management measures and operational conditions \(Chapter R.13\)](#) (ECHA, 2012b) provides supporting guidance on the most common types of risk management measures and use conditions having an impact on exposure. It includes an overview of operational conditions and risk management measures related to exposure of workers, consumers, and the environment.

Exposure models also provide the means for predicting chemical/ material levels (e.g. concentrations) at a specific point in time, in a specific medium and therefore the potential of exposure for human health and the environment. To make their use more practical, models are often integrated into tools with a user-friendly interface (see Annex B. 3. for more information).

The process of gathering data is an iterative process that leads to collection of refined data and higher quality of available data. As more data becomes available, higher tier estimation tools can be used and more realistic scenarios and predictions will be obtained.

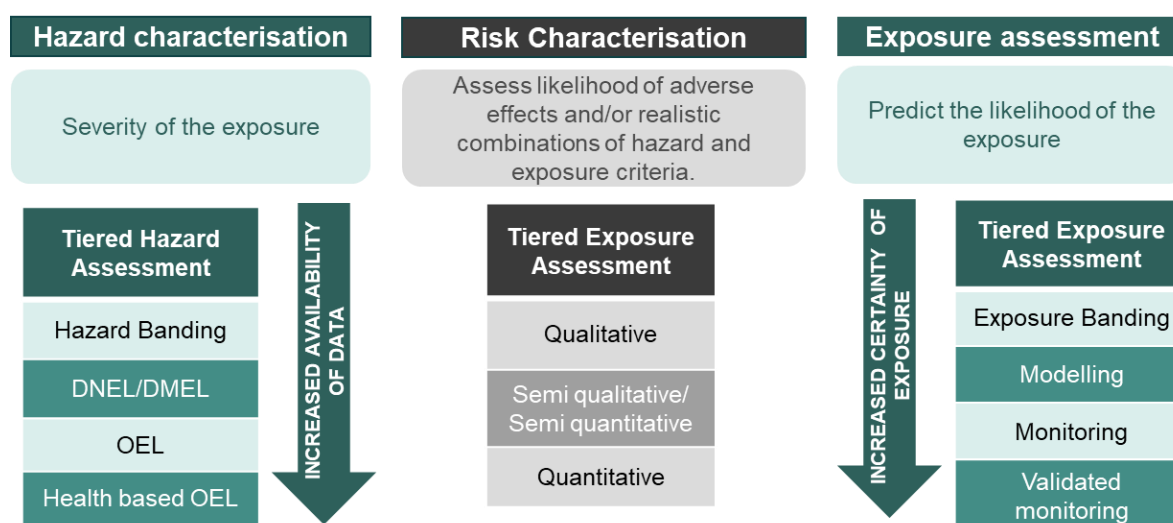
- In Tier 1, exposure is assessed using worst-case assumptions to quickly identify red flags. This tier is intentionally conservative and requires minimal input data (e.g. default values, generic use scenarios).
- In Tier 2, exposure is assessed using more realistic use conditions and risk management measures, refined models, and measured or scenario-specific data are incorporated (real concentrations, frequency of use, or site-specific release factors).
- Tier 3, involves the highest level of refinement, often using quantitative monitoring data, advanced exposure modelling, and occupational/ environmental measurements.

4.3.3. Safety assessment

The risk is characterised as a combination of the chemical/ material hazards characterisation (DNEL, PNEC) and the measured or predicted exposure to the human health and the environment (Figure 18).

For characterising the risk associated to the use the SSbD Practitioner should establish the significant routes of exposure based on the use. Based on this, the measured or predicted exposure should be compared with the tolerable maximum level derived from the available toxicological knowledge from the hazard assessment.

Figure 18. Relevant aspects for the risk characterisation



Source: JRC

Depending on the approaches used, and the available data derived both from both the hazard and exposure assessment, it will be also possible to perform the risk characterisation in a tiered approach, ranging from a qualitative (i.e. lowest tier) to a quantitative characterisation as data becomes available.

When full data sets are lacking, simplified models (e.g., control banding) can be used to perform a qualitative assessment. These models vary in detail and conservatism but support early-stage decisions. Based on the likelihood of the exposure to take place and the severity of the effect different risk levels are assigned (High, Medium-High, Medium, Low-Medium and Low).

Quantitative methods are based on the Risk Characterisation Ratio (RCR), where the exposure concentration is measured or predicted and compared against the tolerable maximum level derived from the available (eco)toxicological knowledge from the hazard assessment (DNEL, PNEC). If the available data indicate that for certain uses the risk is too high, e.g. the DNEL/NOAEL values are exceeded, further refinement is needed either of the hazard assessment or of the exposure assessment (or both).

- Hazard refinement: further testing or higher tier testing is needed, identify the data needs, propose a testing strategy (see Section 4.3.1.1)
- Exposure refinement: The quickest and most cost-effective approach is to improve the realism of the exposure improving information on operational conditions and improving information on risk management. If sufficient exposure information is available, more complex exposure models ('higher tier' models) may be employed to get a more precise exposure estimate. Running such models would normally require the collection of additional information related to the use and use conditions. Exposure campaigns to measure real exposure can be another alternative for the refinement of the exposure.

Uncertainty analysis can be used in the iterations to test the robustness of the risk characterisation, to identify the most uncertain inputs to the entire assessment (whether hazard or exposure related) that influence the risk characterisation, and thereby to decide on the most cost-effective way to collect any additional information needed on these elements to improve the assessment.

4.4. Safety from the life cycle stage and receptor perspective

A holistic safety assessment goes beyond a single chemical safety assessment (Figure 13) and considers safety across life cycle stages—manufacturing, formulation, processing, use, recycling, and disposal and identifies and integrates other aspects related to the protection of receptors (human health and the environment) that are not directly associated with the manufactured chemical or material. These can be, for example, aspects related to other chemicals and materials present in the life cycle stage or other hazard/ risk types (for example, associated with exposure to biological or physical agents).

Therefore, a comprehensive safety assessment considers and integrates other safety aspects such as process safety (system integrity), worker safety (occupational protection), environmental safety (environment protection), and product safety (end-user protection) to ensure that safety is maintained at every life cycle stage and for every affected group (Garmendia Aguirre et al., 2025a).

Process safety focuses on the integrity and stability of the system. It addresses risks such as equipment failure, loss of containment, fire and explosion, uncontrolled reactions, pressure build-up, infrastructure degradation, automation or control system malfunction, and failures during non-routine conditions (start-up, shutdown, maintenance, cleaning) (Center for Chemical Process Safety, 2007; Soter Software, 2026; Ibrahim et al., 2025). The following steps are typically followed:

- HAZID (Hazard Identification) is a high level, qualitative method used to identify potential hazards before detailed design is available. It focuses on recognising risks and is particularly useful during the conceptual design phase.
- HAZOP (Hazard and Operability Study) is the systematic, team-based approach used to analyse processes and systems for deviations from their intended design. It is widely regarded as one of the most effective tools for identifying hazards and operability issues.
- LOPA (Layer of Protection Analysis) is employed as a risk mitigation layer. It is the semi-quantitative risk assessment method that evaluates the effectiveness of existing safeguards and determines whether additional layers of protection are needed. It focuses on the effectiveness of safeguards and layers of protection.

The objective is to prevent major accidents and ensure the process operates within safe limits throughout manufacturing, transport, use, and waste stages.

Worker safety (ILO, 2021) concerns individual exposure to hazards generated by the process and workplace conditions. This includes physical hazards (machinery, confined spaces, noise, heat), ergonomic strain, slips and falls, human error under fatigue or shift work, and risks during maintenance or manual intervention. It also covers training adequacy, supervision, workload, and safety culture. Worker risk may change significantly between routine operations and non-routine tasks.

Environmental safety evaluates aspects such as emissions, waste generation and long-term ecosystem effects. It considers both acute events (spills, releases) and chronic impacts (air emissions, wastewater discharge, solid waste accumulation). This part of the assessment might overlap with process-related sustainability assessment (see section 5.7.), which aims to complement the above stage by also integrating sustainability and ecological aspects that reflect the complexity and the quality of the environment close to the processing plant. This should not be understood as a methodological weakness but a strength and complementarity.

Integrated safety management. Distinguishing these three perspectives (process, worker and environmental safety) ensures that preventing major process accidents (Seveso), protecting individual workers (Occupational Safety and Health), and safeguarding the environment (environmental safety) are addressed with targeted, **stage-specific** controls rather than being treated as a single combined issue (EPSC, 2024). This is complemented with the process related sustainability. (See section 5.7.)

Product safety (EU, 2023; ISO, 2013) in the end-use phase must ensure the protection of both the individual consumer and the surrounding environment, addressing realistic use scenarios, misuse potential, and end-of-life pathways to minimise harm beyond the point of sale. From a **consumer safety** perspective this includes mechanical stability, electrical safety, fire risk, durability, safe packaging, labelling clarity, child resistance, misuse potential, maintenance requirements, and safe end-of-life handling. It also considers vulnerable populations (children, elderly, disabled users), long-term use patterns, interactions with other products, and behavioural factors such as incorrect installation or lack of maintenance. From a possible **environmental safety** perspective at end use, attention shifts to emissions during use, micro-release of materials and impacts during disposal or recycling. Improper disposal, littering, waste mismanagement, or resource-intensive use patterns can also create long-term ecosystem burdens. (See section 5.)

4.5. Examples of Iterative and tiered problem formulation

This section provides examples of the problem formulation supporting the tiered assessment in four SSbD iterations for chemical/material (molecular) (re)design, process (re)design and product (re)design (**Error! Reference source not found.**).

- Early design exploration: Concept & ideation: Qualitative assessment (e.g. TRL 1-2)
- Design optimisation and comparison: Proof of concept: Semi-quantitative assessment (e.g. TRL 3-4)
- Decision-ready safety justification: Pre-demonstration: Quantitative assessment (e.g. TRL 5-6).
- A confirmatory quality assessment for industrial-scale safety validation/ demonstration is included as a fourth iteration. This confirmatory quantitative assessment focuses on verifying and validating the quantitative predictions using data generated under realistic or operational conditions (e.g. industrial operations, real-use exposure monitoring). It tests the robustness of the quantitative assessment, confirming that the predicted safety margins remain valid when variability, scale-up effects, and real-world use patterns are considered (e.g. TRL 7-8).

Problem formulation and safety assessment is inherently iterative in SSbD. Assessment results should be systematically evaluated and feed back into the scoping analysis and problem formulation for the next iteration where safety assessment will be refined in a higher tier assessment approach.

Table 5a. Iterative problem formulation for chemical/material (re)design (molecular).

Innovation	Molecular (re)design of a functional organic molecule (e.g. surfactant / additive) to reduce hazard, persistence, and exposure potential while maintaining technical function.
Desing level	Molecular (re)design
Design action	Modification of molecular structure (functional groups, chain length, cleavable bonds).

PROBLEM FORMULATION	Qualitative assessment	Semi-quantitative assessment	Quantitative assessment	Confirmatory quantitative assessment
Purpose	Explore whether molecular redesign could plausibly reduce key safety concerns. - Identify dominant safety concerns - Define design-relevant safety hypotheses	Support comparative safety-driven design decisions. - Identify the safest viable candidate - Rank candidates by safety relevance - Identify key risk drivers and uncertainties	Demonstrate that the molecule is safe-by-design within defined conditions of use. - Confirm safety targets are met - Define residual risks and safe-use conditions	Confirm that real-world exposure and fate data support prior safety conclusions. - Verify exposure estimates - Confirm safety margins - Identify unexpected transformation or interaction effects
Decision context	- Early screening, no exclusion claims - Focus on intrinsic properties and fate	- Comparison of molecular variants under the same system assumptions - Excludes full regulatory risk assessment	- Risk-based safety assessment - Includes degradation products	- Validation of assumptions used - Confirmation under operational variability
Scope	Partial coverage, high uncertainty accepted. - Life cycle stage: Molecule in intended use phase (qualitative) - Application type: Potentially dispersive use - Environmental exposure compartments: Water (primary)	Most safety aspects addressed at screening depth. - Life cycle stage: Molecule during production and use - Use scenarios: Defined (professional) - Release pathways: Identified qualitatively - Receptors: Aquatic organisms, workers (screening)	All safety aspects addressed within a defined system. - Life cycle stage: Production → use → end-of-life - Use conditions: Quantified - Exposure routes: Environmental and occupational - Receptors: Identified and justified	Safety performance validated in operational context. - Life cycle stage: Full lifecycle under realistic production and use conditions - Scale: Industrial production and real-use application - Exposure context: Measured occupational and environmental exposure

PROBLEM FORMULATION	Qualitative assessment	Semi-quantitative assessment	Quantitative assessment	Confirmatory quantitative assessment
	Receptors: Environment (generic), users (generic)			Receptors: Workers, users, local environment, vulnerable groups
Approach	- Intrinsic hazard: Qualitative (alerts, known concerns) - Environmental fate: Conceptual (plausible degradability) - Exposure potential: Very coarse (dispersive vs contained) - Risk perspective: Not yet risk-based	- Intrinsic hazard: Relative ranking (QSAR, read-across) - Environmental fate: Estimated degradation ranges - Exposure: Scenario-based (qualitative/semi-quantitative) - Risk perspective: Comparative (not absolute)	- Intrinsic hazard: Data-driven - Environmental fate: Measured + modelled - Exposure: Quantified scenarios - Risk perspective: Explicit risk-based	- Intrinsic hazard: Confirmed with production-grade material - Environmental fate: Validated under real conditions - Exposure: Measured and model-validated - Risk perspective: Operationally confirmed
Criteria	- Presence of structural alerts - Conceptual degradability - Expected exposure relevance	- Relative persistence - Relative toxicity potential - Exposure relevance under defined use scenarios	- Effect thresholds (e.g. NOEC, EC50, PNECs, DNELs)¹ - Exposure estimates - Risk characterisation metrics (RCR)	- Measured exposure vs predicted exposure - Confirmed risk characterisation ratios - Stability of degradation profile - Absence of new hazard drivers

¹ Lethal Concentration 50% (LC50), Lethal Dose 50% (LD50), No Observed Adverse Effect Level (NOAEL), No Observed Adverse Effect Concentration (NOAEC), Derived No Effect Level (DNEL), Occupational exposure limits (OELs), Predicted No Effect Concentration (PNEC)

PROBLEM FORMULATION	Qualitative assessment	Semi-quantitative assessment	Quantitative assessment	Confirmatory quantitative assessment
Data approach	- Literature knowledge - Expert judgement - In silico alerts (screening level)	- QSAR and read-across - Estimated half-lives - Categorised exposure estimates - Weight-of-evidence	- Experimental toxicity and fate data - Exposure modelling - Conservative assumptions - Sensitivity analysis	- Monitoring data - Workplace measurements - Environmental sampling - Post-scale-up analytical verification - Targeted sensitivity re-analysis
Expected Output	“Go / adjust / stop” design decision - Safety hypotheses to test in next iteration	- Ranked list of molecular candidates - Selection of lead design for further development	- Quantitative safety justification - Conditions and limitations transparently stated - Hazard classification (H criteria verification)	- Operational safety confirmation - Refined safe-use conditions if needed - Evidence package for regulatory or market assurance

Table 5b. Iterative problem formulation for process (re)design.

Innovation	(Re)design of a chemical manufacturing process to reduce hazard, exposure, and accident risk , while delivering the same product quality.
Design level	Process (re)design
Design action	Changes in operating conditions, solvents, intermediates, containment, and process configuration.

PROBLEM FORMULATION	Qualitative assessment	Semi-quantitative assessment	Quantitative assessment	Confirmatory quantitative assessment
Purpose	Explore whether process redesign can plausibly reduce safety risks compared to the baseline. - Identify dominant safety drivers - Inform selection of safer process routes	Support comparative selection of process designs based on safety performance. - Rank process options by safety relevance - Identify critical process safety parameters	Demonstrate that the redesigned process is safe-by-design under defined operating conditions. - Confirm risk acceptability - Define operational safety limits	Validate that industrial-scale risks remain within acceptable limits - Confirm predicted failure frequencies - Validate exposure controls - Identify emergent risks

PROBLEM FORMULATION	Qualitative assessment	Semi-quantitative assessment	Quantitative assessment	Confirmatory quantitative assessment
Decision context	• Early screening of process concepts • No quantitative risk estimation	• Comparison under defined operating scenarios • Excludes full quantitative risk assessment	• Full process safety assessment • Includes abnormal operation and failure modes	• Verification of safety under real operating conditions • Inclusion of human factors and operational variability
Scope	Partial coverage of safety aspects; high uncertainty accepted. • Life cycle stage: Core process steps (qualitative) • Process type: Batch vs continuous (conceptual) • Hazard sources: Reactive intermediates, solvents • Receptors: Workers, environment (generic)	Most safety aspects addressed at screening depth. • Life cycle stage: Unit operations at lab/pilot scale • Operating conditions: Defined ranges • Exposure pathways: Identified • Receptors: Workers, local environment	All safety aspects addressed for the defined process system. • Life cycle stage: Full process (start-up → normal operation → shutdown) • Scale: Pilot or demonstration • Exposure routes: Occupational and environmental • Receptors: Identified and characterised	Process safety performance confirmed under industrial conditions. • Life cycle stage: Full industrial process including start-up and shutdown • Scale: Demonstration or first industrial plant • Operational variability: Real operating ranges • Receptors: Workers, surrounding environment, contractors
Approach	• Intrinsic process hazard: Qualitative (high/medium/low) • Exposure potential: Conceptual (open vs closed systems) • Accident potential: High-level identification • Risk perspective: Not yet risk-based	• Intrinsic hazard: Comparative (process conditions) • Exposure: Scenario-based (semi-quantitative) • Accident potential: Screening-level analysis • Risk perspective: Relative risk comparison	• Intrinsic hazard: Quantified • Exposure: Quantified • Accident risk: Quantitative • Risk perspective: Explicit and documented	• Intrinsic process hazard: Verified at industrial scale • Exposure: Measured during operation • Accident risk: Quantitatively reassessed • Risk management: Operational and documented
Criteria	• Presence of highly hazardous steps (SSbD H Criteria) • Potential for uncontrolled releases • Worker exposure relevance	• Relative accident likelihood • Exposure categories • Severity of credible failure scenarios	• Quantitative risk metrics • Exposure limits • Accident consequence thresholds	• Quantified incident likelihood • Measured worker exposure vs limits • Confirmed safety integrity levels • Stability of process safety en-

PROBLEM FORMULATION	Qualitative assessment	Semi-quantitative assessment	Quantitative assessment	Confirmatory quantitative assessment
Data approach	- Process knowledge - Hazard identification (conceptual HAZID) - Expert judgement	- Screening Hazard and Operability Study (HAZOP) - Categorised exposure estimates - Semi-quantitative risk matrices	- Detailed Hazard and Operability Study (HAZOP) / Layer of Protection Analysis (LOPA) - Quantitative exposure modelling - Failure probability analysis	- Operational monitoring data - Incident and near-miss analysis - Updated quantitative risk assessment - Validation of LOPA/HAZOP as-
Expected Output	- Process routes retained or discarded - Safety hypotheses for next iteration	- Preferred process configuration - Defined safety-critical parameters	- Quantitative process safety justification - Defined safe operating envelope - Residual risks and control measures clearly stated	- Confirmed inherently safer process design - Updated operational safety documentation - Final safety case for full deployment

Table 5c. Iterative problem formulation for product (re)design.

Innovation	(Re)design of a formulated product (e.g. coating, cleaning product, consumer or professional chemical product) to reduce hazard and exposure during use , while maintaining intended performance.
Desing level	Product (re)design
Design action	Changes in formulation composition, concentration, physical form, packaging, and delivery mode.

PROBLEM FORMULATION	Qualitative assessment	Semi-quantitative assessment	Quantitative assessment	Confirmatory quantitative assessment
Purpose	Explore whether product redesign can plausibly reduce safety concerns in the intended use context. - Identify dominant safety concerns - Define product-level safety hypotheses	Support comparative selection of product designs based on safety performance. - Rank product options by safety relevance - Identify exposure-dominant design features	Demonstrate that the product is safe-by-design under defined conditions of use. - Confirm safety targets are met - Define conditions and limitations of safe use	Verify that real-use exposure aligns with predicted safe-use conditions. - Confirm safety margins - Detect unexpected exposure routes - Refine risk communication if needed

PROBLEM FORMULATION	Qualitative assessment	Semi-quantitative assessment	Quantitative assessment	Confirmatory quantitative assessment
Decision context	• Early screening of product concepts • Focus on use-related exposure and hazard	• Comparison under defined use scenarios • No final regulatory risk assessment	• Quantitative safety and exposure assessment • Includes foreseeable misuse	• Post-prototype validation • Inclusion of foreseeable misuse patterns
Scope	Partial coverage of safety aspects; high uncertainty accepted. • Life cycle stage: Product during intended use (qualitative) • Product type: Consumer or professional • Exposure context: Direct contact, emissions during use • Receptors: Users, environment (generic)	Most safety aspects addressed at screening depth. • Life cycle stage: Product during production and use • Use scenarios: Defined (consumer vs professional) • Exposure pathways: Identified and described • Receptors: Users, environment (screening)	All safety aspects addressed within a defined product system • Life cycle stage: Production → use → disposal • Use conditions: Quantified and representative • Exposure routes: Identified and quantified • Receptors: Identified (users, environment)	Product safety confirmed under real-use conditions. • Life cycle stage: Production → real use → disposal • Use variability: Real consumer/professional behaviour • Exposure context: Measured or post-launch monitored • Receptors: Users, environment
Approach	• Intrinsic hazard: Qualitative (ingredient-based) • Exposure potential: Conceptual (use pattern) • Use-related risk: Qualitative • Risk perspective: Not yet risk-based	• Intrinsic hazard: Comparative (formulation-based) • Exposure: Scenario-based (semi-quantitative) • Use-related risk: Screening-level • Risk perspective: Relative risk comparison	• Intrinsic hazard: Data-driven • Exposure: Quantified • Use-related risk: Risk-based • Risk perspective: Explicit and transparent	• Intrinsic hazard: Confirmed for final marketed formulation • Exposure: Validated in real-use scenarios • Use-related risk: Confirmed within acceptable margins • Risk management: Embedded and communicated
Criteria	• Presence of hazardous ingredients (SSbD H criteria) • Likely exposure routes	• Estimated user exposure • Toxicity category of formulation	• Effect thresholds (e.g. DNELs, PNECs)² • Exposure estimates	• Measured exposure vs acceptable thresholds • Observed incident data

² Derived No Effect Level (DNEL), Occupational exposure limits (OELs), Predicted No Effect Concentration (PNEC)

PROBLEM FORMULATION	Qualitative assessment	Semi-quantitative assessment	Quantitative assessment	Confirmatory quantitative assessment
	Potential for misuse	Margin between exposure and effect levels (screening)	Risk characterisation ratios (RCR)	Stability of risk characterisation ratios
Data approach	- Ingredient hazard knowledge - Use-pattern assumptions - Expert judgement	- Exposure estimation tools - Read-across and ingredient data - Weight-of-evidence	- Toxicological and ecotoxicological data - Exposure modelling - Conservative assumptions - Uncertainty analysis	- Field monitoring studies - Post-market exposure measurements - Feedback and surveillance data - Reassessment of exposure models
Expected output	- Product concepts retained or rejected - Safety-relevant redesign directions identified	- Preferred product formulation selected - Safety-critical design elements identified	- Quantitative safety justification - Clearly defined safe-use conditions - Transparent statement of residual risks	- Operational safety validation - Updated safe-use guidance if needed - Final safety assurance for wide deployment

Source: JRC

4.6. FAQs on the safety assessment

What is the difference between the scoping analysis and problem formulation for the safety assessment?

While the scoping analysis supports the implementation of the SSbD principles in the context of an innovation and provides the holistic safety perspective and considerations, problem formulation is a subsequent step, that complements the scoping analysis with the robust targeted and focused safety assessment of the innovation. The difference comes down to scope and depth.

Can I apply a tiered approach in the SSbD safety assessment?

Safety assessment in SSbD is inherently iterative. Completeness and robustness of the assessment increases as innovation progresses, more information is available, and data is generated to fill the gaps in a tiered approach for the different components and the overall safety assessment. However, these tiers do not necessarily align. Tier 1 in hazard identification does not have to align with tier 1 in exposure estimation. The tiers define the level of depth and complexity in the assessment process and represent the progressive steps in analytical detail, data requirements, quality needs and decision confidence.

What are the references I can use in innovation for safety considerations in SSbD?

A robust safety assessment is a systematic and scientifically grounded process that relies on high-quality, reproducible data generated through validated methods, often guided by internationally recognised standards and regulatory frameworks enforced by competent authorities. It integrates hazard identification with exposure assessment across relevant scenarios to evaluate whether a chemical or material can be used safely under defined conditions. A robust safety assessment is

absolute and full. However, in the context of innovation, and when full data is not available for a full and robust assessment, different available references can be used for the purpose of supporting decision-making as the innovation progresses:

- **In early innovation stages**, safety references are those that identify red-flags or concerns with regards to hazards (specific structure, functional groups, hazard classification) and exposure (potential widespread, physio-chemical properties).
- **In mid-innovation stages**, when the objective is to optimise the innovation, alternatives are compared against each other based on estimated or predicted safety parameters.
- **At later innovation stages**, when safety needs to be verified, the tolerable maximum exposure levels (DNEL, PNEC) are the reference values against which the predicted or measured exposure, is compared to derive the Risk Characterisation Ratio (RCR). These exposure levels are derived from (eco)toxicological data containing information for the specific chemical, hazard endpoint, exposure route, effect, and receptor (human population and environmental compartment).

Is hazard classification the same as safety assessment?

No, they differ – hazard classification is an outcome of the hazard assessment, one of the safety assessment components. Hazard classification on its own is not sufficient to assess and determine safety. However, where hazard is the main driver of safety concern and when a hazard classification is available, it can be used to support decision-making in early innovation stages.

In cases of complex/ multicomponent chemicals and materials, a good characterisation

and composition is important to derive the classification of the chemical or material, based on their components.

Are the safety considerations in environmental sustainability assessment equal to a safety assessment?

No, they are not the same. Environmental sustainability assessment can be applied to systematically identify potential safety issues in the life cycle, by applying specific metrics (e.g. for toxicity and ecotoxicity impact categories), while safety assessment is systematic and detailed and produces evidence-based robust conclusions about safety.

How do I perform safety assessment when I have complex mixtures or materials?

Safety assessment of complex mixtures and materials remains challenging because most New Approach Methodologies (NAMs) and standardised test methods have been developed for single substances with a well-defined molecular structure. For complex

materials, a weight-of-evidence approach is often required, combining physicochemical characterisation, information on composition and variability, read-across from similar materials, exposure assessment, existing toxicological data, and targeted NAMs, where applicable.

The assessment should focus on the components, fractions, or properties most relevant to exposure and biological activity, rather than relying solely on methods designed for pure substances.

Where uncertainties remain significant, the assessment should explicitly document their impact on the conclusions and avoid overinterpretation of results. Since complex mixtures and materials may contain multiple constituents, transformation products, or poorly characterised fractions, safety evaluations should be performed on a case-by-case basis and may require integrating multiple lines of evidence rather than deriving conclusions from a single test or endpoint.

5. Environmental Sustainability Assessment

AIM OF THE SECTION:

This section gives an introduction on Environmental Sustainability Assessment (ESA), with reference to the Technology Readiness Level (TRL) and associated level of data available. ESA in SSbD uses Life Cycle Assessment (LCA) as its reference methodology, aiming - as a final goal- at conducting an assessment following the EC Environmental Footprint (EF) method which is the recommended LCA method of the European Commission (EC, 2021a).

It guides the practitioner in performing a tiered ESA according to the maturity of the innovation, including:

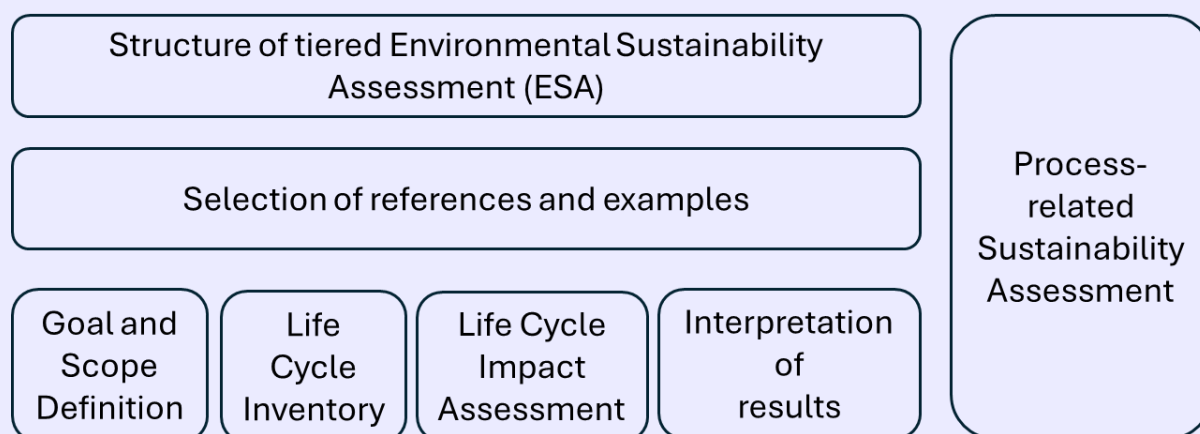
- Narrowed down system boundaries (under specific conditions);
- Data generation and collection;
- Narrowed down assessment indicators;
- Proposed reference to guide comparisons;
- Guidance for process-related sustainability assessment; and
- Interpretation of results to guide innovation.

Adjustments to the described tiered LCA might occur over progressive refinements.

Additionally, ESA introduces the assessment of process-related sustainability, which offers the possibility to zoom in on specific industrial processes along the value chain, in order to estimate those impacts that are site-specific. The method proposed takes its inspiration from Environmental Impact Assessment (EIA) approaches.

Further information on ESA is included in Annex C, D and E.

Figure 19. Structure of the environmental sustainability assessment section



Source: JRC

5.1. Structure of the tiered environmental sustainability assessment (ESA)

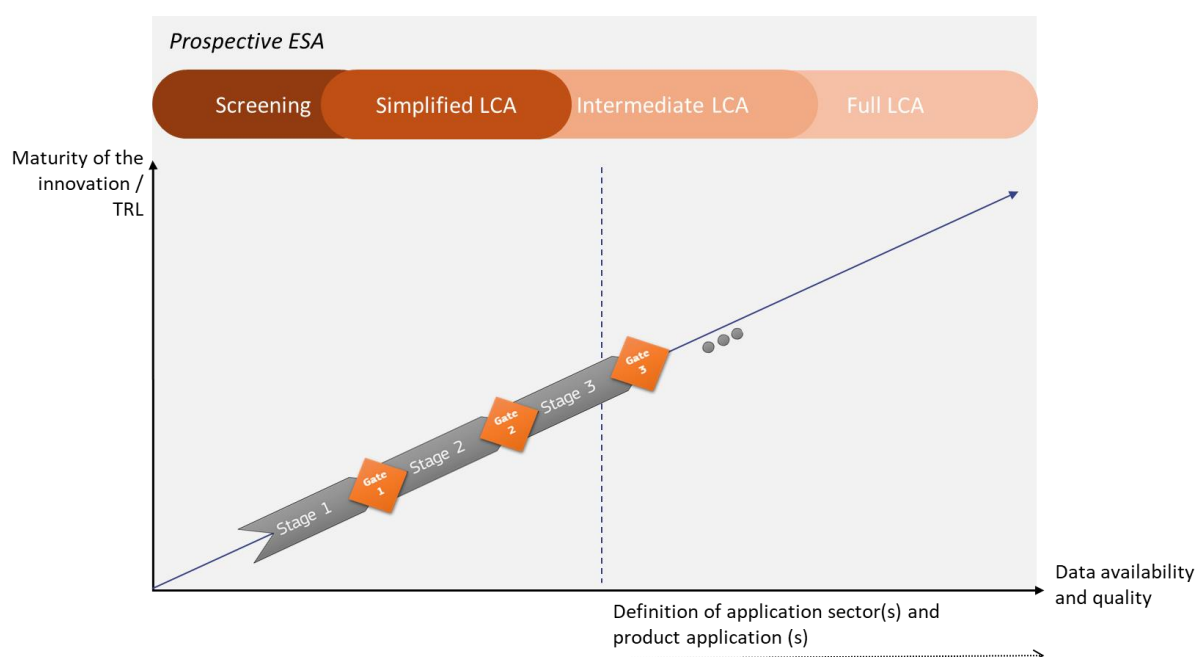
From a methodological perspective, the ESA applied in the (re)design of chemicals/materials aligns with the type of LCA known as [Prospective LCA](#). Hence, the following aspects should be considered, to frame the assessment alongside the innovation stages of a chemical/material:

- The degree of *knowledge of the innovation technology*, noting that this will increase as the innovation proceeds. At low maturity of the innovation, it is common to consider, for instance, narrower system boundaries and fewer impact categories. Also, assumption may have to be made regarding the data used, or lower quality data may be input, of necessity, to the model. lower quality.
- The *temporal scale* (timeline) between the start of the innovation and the placing of the end-product on the market, as result of the innovation process. This needs to be reflected in the background data used to correctly include foreseen future changes of background aspects (e.g. changes in the electricity mix) (e.g., Sacchi et al., 2022).

These aspects affect the four steps of an ISO-compliant LCA (i.e. Goal and Scope definition, Life Cycle Inventory (LCI), Life Cycle Impact Assessment (LCIA), and Results Interpretation) (ISO, 2020), and should be reflected in the assessment, accordingly.

According to the outcome of the scoping analysis, scenarios can be defined to tailor the safety and sustainability assessments, based on the degree of maturity of the innovation process being considered and related data availability. Figure 20 shows the [tiered approach of the \(prospective\) ESA](#), which includes four main blocks: **screening assessment**, **simplified LCA** (fitting into the simplified SSbD assessment), **intermediate LCA** (fitting into the intermediate SSbD assessment), and **full LCA** (fitting into the full SSbD assessment). The full LCA reflects the Product Environmental Footprint (PEF,) which is the recommended LCA method of the European Commission (EC, 2021a). Table 5 provides an overview of the main aspects to build the assessment.

Figure 20. Tiered approach of the increasing completeness of the (prospective) ESA.



Source: JRC

Table 5. Summary of the main aspects of the tiered approach for the ESA

Tiered ESA		Screening assessment	Simplified LCA	Intermediate LCA	Full LCA
Applicability		• Low maturity of innovation • Data from laboratory most likely only from the innovator • High uncertainty of the assessment • Low/medium possibility to engage with the other actors of the value chain • Un/Defined application(s)	• Usually low maturity of innovation • Data from laboratory most likely only from the innovator • High uncertainty of the assessment • Low/medium possibility to engage with the other actors of the value chain • Un/Defined application(s)	• Increasing maturity of the innovation • Data from industrial or pilot scale • Medium/High uncertainty of the assessment • Medium/high possibility to engage with the other actors of the value chain • Defined application(s)	• High maturity of the innovation • Data from industrial scale • Low uncertainty of the assessment • High possibility to engage with the actors of the value chain • Defined application(s)
Main characteristics		• It helps to identify hotspots on the key selected design principles – and related indicators (refer to Table 11 of <i>Garmendia Aguirre et al. 2025a</i>). • It helps prioritizing or screening (re)design options to further investigate later on during the innovation through the LCA. • The environmental impact assessment might not be comprehensive.	• It helps to identify the most important life cycle stages and processes for data refinement and thus guides the optimal use of effort and resources. • Knowing the product or sector application of the chemical/material under development, it is possible to create scenarios describing the possible variabilities, for instance in terms of geography or products.	• Continuous iterative adjustment of the simplified LCA. • Refinements include among others primary data collection, data gaps filling, impact categories, and expansion of the system boundaries from cradle-to-gate to cradle-to-grave. • Effort regarding the collection of primary data for LCI via in-house data collection, enhanced engagement with suppliers and/or downstream users, making specific data requests, etc.	• Final adjustments of the intermediate LCA. • The full LCA includes adjustments that allows the compliance with the Recommendation of the European Commission to perform the LCA. • Adjustments mostly regard LCI refinements, maximization of the of the value chain engagement, improvement of the use and end-of-life phases modelling.
Goal and scope definition					
Functional Unit (see	<i>Defined application</i>	Unit mass of the chemical/material (i.e. declared unit).	As in PEF definition.		

Tiered ESA		Screening assessment	Simplified LCA	Intermediate LCA	Full LCA
Section 5.3.1)	Undefined application		Unit mass of the chemical/material (i.e. declared unit).	As in PEF definition.	
System boundaries (see Section 5.3.2)	Defined application	It reflects the assessed indicators for the applied design principles, e.g. Gate-to-gate, Cradle-to-gate + end of life aspects	Cradle-to-grave, OR Cradle-to-grave <i>with scenarios</i> (if multiple application sectors are considered).		
	Undefined application		Cradle-to-gate.	Cradle-to-grave OR Cradle-to-grave with scenarios (if multiple application sectors are considered).	
Reference (See Section 5.2)		Proxy, representative system, desired target (optional).	Benchmark, representative system, desired target (optional).		Representative system, desired target (optional).
LCI (further guidance in Section 5.4)		• Data generation supported by laboratory tests or modelling scenarios. • Scenarios reflecting different production layouts or product applications. • Information on the recyclability and circularity should be prioritized.	• Data generation supported by laboratory tests or modelling scenarios. • Scenarios reflecting different potential product applications. • Information on the recyclability and circularity should be prioritized.	• Primary data via enhanced engagement with suppliers and/or downstream users, making specific data requests. • Scenarios reflecting different potential product applications.	• Primary data via enhanced engagement with suppliers and/or downstream users, making specific data requests.
LCIA (further guidance in Section 5.5)		• The assessed indicators reflect the chosen design principles to follow, which may (partially) cover the impact categories of the LCA. • Identification of key indicators considering the relevance of the related impact category, based on expert judgment/qualitative assessment	• Narrowed to the most relevant environmental aspects (potential outcome of the Scoping Analysis – see Section 3.5) • Focus on impact categories that are relevant for the analysed system, extending the assessment beyond the initial	Extended to the 16 environmental impact categories of the Environmental Footprint recommendations (EC, 2021a).	

Tiered ESA	Screening assessment	Simplified LCA	Intermediate LCA	Full LCA
	of the possible areas of impact generated by the innovation.	impacts assessed in screening assessment and/or the process-related sustainability indicators.		
Interpretation of results (further guidance in Section 5.6)	- Identification of key indicators among the ones provided in table 11 of Garmendia Aguirre et al. 2025, as proxies of impact categories of <i>the</i> EF recommendations (EC, 2021a). - Identification of potential hotspots due to variation compared to reference and prioritisation R&D efforts.	- Data quality and refinement for the Life Cycle Inventory (LCI) of the LCA model, and - Identification of potential hotspots that should provide insights to the innovation	- Data quality and refinement for the Life Cycle Inventory (LCI) of the LCA model, and - Identification of potential hotspots that should provide insights into the innovation	- Interpretation based on Section 6 of the EF methodology (EC, 2021) - Aggregation of the results in four environmental categories is possible

Source: JRC

5.2. Selection of the reference (chemical, material or process)

Environmental sustainability assessment (ESA) is a comparative method and therefore always requires a reference chemical, material or process against which to compare the intended innovation, for the evaluation. The [reference system](#) allows practitioners to assess the environmental sustainability performance of the SSbD system under assessment by comparing it to another system. The SSbD system (i.e., the innovation-based system being explored, etc) may perform better or worse than that of the reference system, and ESA allows the practitioner to see this relative performance for each of the indicators or impact categories.

There are no strict or single rules for defining the reference system. The following paragraphs give guidance as to its selection throughout the innovation process. Considering the relevance of the choice of a reference chemical or material for the final results, it is important that the choice is carefully made, fully explained and communicated in a transparent manner, preserving an audit trail.

Alongside the definition of the reference system, the criteria presented in Table 10 of the 2025 SSbD framework (Garmendia Aguirre et al., 2025a) help to interpret the results by showing the comparative performance of the new and reference systems. In other words, it should answer the question: “how much better or worse is the SSbD system against the reference system?”

The available references are defined as follows, adapted from the 2025 SSbD framework (Garmendia Aguirre et al., 2025a).

- **Proxy reference:** it compiles reference values for the key aspects of a generic chemical reaction, such as mass balance or energy consumption. It can be built upon the selected indicators of the design principles.
- **Benchmark:** it refers to the average environmental performance of the chemical life cycle following the definition provided by the PEF Recommendation (EC, 2021a) (for more details see Annex D).
- **Representative system:** it represents either the SSbD system that the innovator aims to improve upon (i.e., the *status quo*), or a more general existing system, e.g. reflecting an average situation in a region, or a particular production plant. It may be built using primary data and information or, when not available, from literature/ subscription LCA software packages, etc.

A representative system may reflect either (i) general existing systems, such as situations observed in companies or countries, or (ii) the innovator’s actual situation prior to the implementation of the innovation (i.e. *status quo*). Where the representative system reflects the *status quo*, data should primarily be based on real, observed data. Background system data may be supplemented with information from literature sources where necessary. The representative system, and its underlying data, should remain unchanged throughout the innovation and the assessment, since the aim is to provide a stable and robust reference system, reflecting the real situation. The *status quo* may be used for comparison in two cases: (1) when deciding whether to replace an existing chemical, process or product with a different one (this condition may occur in each stage of the innovation), or (2) when comparing results against the original starting point after refining an intermediate life cycle assessment (LCA).

- **Desired target:** optionally, a target may be set by the SSbD practitioner, which the revised system aims to achieve – for instance, the design objective could be a reduction of resource use by 30% compared to the benchmark or representative system.

Once the reference system has been identified, scores and classes of performances may be used as criteria to evaluate the LCA result of the chemical/ material/ process/product under assessment for each impact category (Figure 25 and Table 10 of the SSbD framework) (Garmendia Aguirre et al., 2025a). The results of the assessment can be reported in a SSbD assessment dashboard, to inform the subsequent decision-making stage(s), in accordance with the decision-making rules established at the scoping stage.

To summarise, Figure 21 represents how the SSbD system under assessment can be compared against a reference defined in ESA. Here, better or worse performance is represented by different colours. More precisely, it provides a conceptual example of an evaluation across multiple SSbD systems (namely A, B, and C). The reference is shown at the base of Figure 21, while a table on the right summarises the results using a colour code based on the defined criteria. The colour coding indicates how each system performs compared to the reference system. In addition, Box 5 provides an overview on how the reference system can be defined for the tier ESA

Figure 21. Comparative ESA evaluation of multiple SSbD systems against a reference system via colour coding, reflecting the defined criteria.

SSbD system	Indicator 1	Indicator 2	Indicator 3	Indicator 4
A	Red	Green	Yellow	Green
B	Red	Yellow	Green	Green
C	Red	Yellow	Green	Yellow
Reference	Yellow	Yellow	Yellow	Yellow

Source: JRC

Box 5. Definition of a reference system in tier ESA.

In the **screening assessment**, proxy reference systems may be defined, based on (1) the physio-chemical properties, crucial for ensuring key functionality, (2) design principles (e.g. SSbD 1 material efficiency), and/or (3) target performance level(s) on sustainability aspects should be defined with reference to an equal declared unit (see section 5.3.1 and **Error! Reference source not found.**). At low innovation/ TRL maturity, a **simplified LCA** is appropriate to use, which can rely on the benchmark, and/ or a predefined target (e.g. a 10% reduction in Climate change impacts compared to a reference system with an identical functional unit – see section 5.3.1). As more data become available over time, a representative system, may be defined and used as the reference in the subsequent stages. An **intermediate LCA** is appropriate to use to evaluate the system, e.g. at pilot scale. Here, the reference system is refined, and the detail of the assessment uses actual measured data, giving impact results representing the *status quo*. Subsequently, **full LCA** results can be generated, based on the *status quo* or existing systems, described from literature or real (primary) data. Additional desired targets (e.g. a 10% reduction in water use) may be also defined relative to the reference system and functional unit (see section 5.4.1 for additional details).

5.2.1. Example of defining a reference system

This section provides an example of defining a reference system. It is based on applying SSbD to the redesign of a membrane, considering the three levels of (re)design: molecular, process, and product.

The illustrative example chosen is that of a membrane, which is used to remove organic micropollutants (OMPs) in water purification. The example takes its inspiration from Lu et al. (2025), who highlight the role of functional groups in the relative performance of the techniques examined in removing OMPs. Production of the membrane needed to provide the water purification function involves dissolving a polymer in a solvent, casting it onto a support, and inducing polymer precipitation via water immersion, followed by solvent evaporation. Functional coatings are then applied to improve the membrane's properties, such as resistance to fouling, which helps to maintain performance and to give an extended lifespan to the membrane. During use, the membrane requires cleaning with water and chemicals to sustain efficiency. At the end of life, the membrane is typically incinerated or landfilled, although reuse of the membrane in lower-performance applications may be possible.

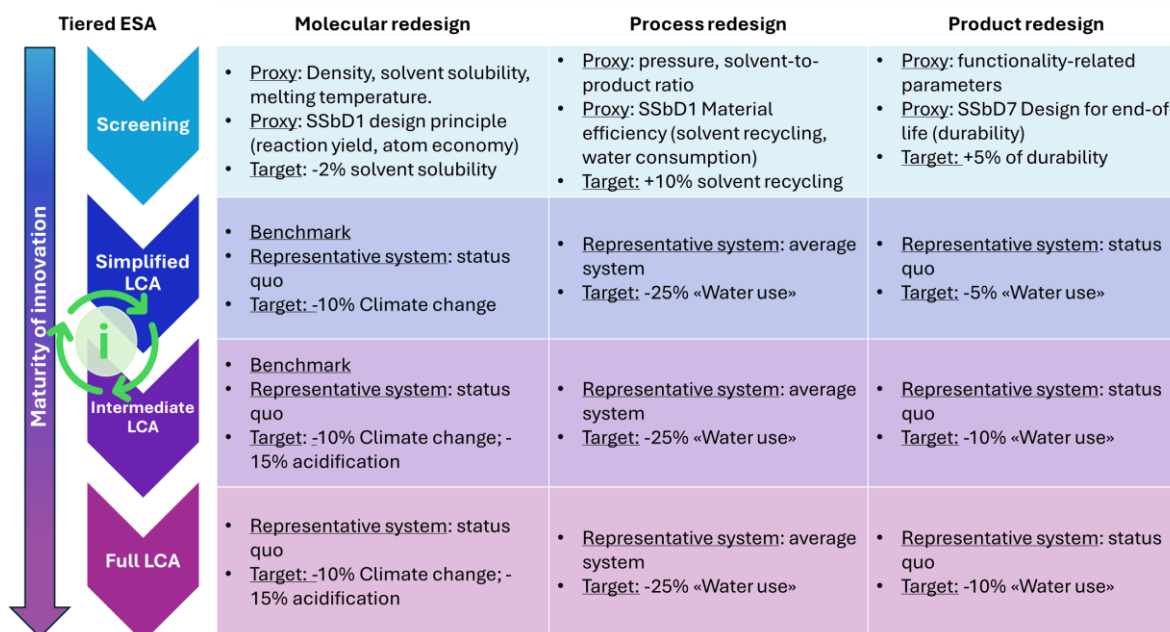
The following (re)design objectives for the membrane are envisaged:

- Molecular redesign: to change the membrane's polymeric composition, to thus improve the OMP–membrane interactions, and to enhance its efficiency, considering the environmental impacts of raw materials.
- Process redesign: to optimise the consumption of water and other auxiliary resources as well as their management and treatment, after use.
- Product redesign: improving the production process of the membrane (i.e. the use phase of polymeric raw materials) by optimising the consumption of water and other auxiliary resources. Secondly, design elements for enhancing durability are examined and proposed, to minimise the membrane's environmental footprint, with a particular focus on the related water use to achieve/ maintain/ improve the required functionality.

This example is purely indicative; it does not represent a real case study with all the necessary details that would need to be assessed, since that would require specific knowledge to provide effective and feasible corrective actions for membrane improvement. In addition, it should be noted that in a real innovation context, a clear separation of the three redesign levels might not exist, which might instead overlap with each other.

Figure 22 gives a visual summary of how the reference systems can be applied for the three levels of redesign, using the tiered approach of environmental sustainability assessment (ESA), in line with the progress of the innovation (see Section 5.1 for more details).

Figure 22. Available references listed for different tiers of the ESA in the example of molecular, process, and product (re)design.



The circled green “i” symbol indicates that design and assessment iterations are performed in that particular stage.

Source: JRC

Molecular redesign, in this example, focuses on the membrane material composition. In the screening assessment, proxy references may be used, based on process parameters such as (e.g. density, solvent solubility, melting temperature), together with design principles such as material efficiency (e.g. reaction yield, atom economy). Targets may also be defined (e.g. a 2% reduction in solvent solubility), always related back to the identical functional unit that has been set. At low maturity, simplified LCA is appropriate to use, often based on laboratory data which can be compared to representative systems via literature or industrial data. For example, results may indicate a 10% reduction in climate change for the same functional unit, which could be formalised as a target, relative to the selected reference system (however, bearing in mind that the potential subsequent scale-up from laboratory to industrial scale may imply relative differences in inputs, outputs and efficiencies). As the innovation matures, the same references can be maintained in intermediate and full LCAs, enabling comparison with the *status quo* references system and tracking improvements over successive iterations.

Process redesign focuses on the membrane production stage, in this example. In the screening assessment, proxy references may be used, based on process parameters such as (e.g. pressure, solvent-to-product ratio), together with design principles such as material efficiency (e.g. solvent recycling, water consumption, for which). Targets may also be defined (e.g. a 10% increase in solvent recycling, etc), always related back to the identical functional unit that has been set. At low maturity, simplified LCA is appropriate to use, often based on laboratory data which can be compared to representative systems via literature or industrial data. For example, results may indicate a 25% reduction in water use for the same functional unit, which could be formalised as a target, relative to the selected reference system (however, bearing in mind that the potential subsequent scale-up from laboratory to industrial scale may imply relative differences in inputs, outputs and efficiencies). As the innovation matures, the same references can be maintained in intermediate

and full LCAs, enabling comparison with the *status quo* references system and tracking improvements over successive iterations.

Product redesign focuses on the membrane's functional and environmental performance, in this application. Screening assessments may rely on proxy references, such as functional parameters (e.g. pore geometry), and design principles (e.g. design for EoL, including durability). Targets may be set (e.g. a 5% increase in durability) for the same declared functional unit. Simplified LCA at a laboratory scale (results of the membrane, where system boundaries are cradle-to-gate + complemented with end-of-life (EoL)) can be compared to representative systems (e.g. existing membranes). The same references are maintained, while intermediate LCA may adopt stricter targets (e.g. +10% durability) and full LCA confirms performance at industrial scale.

5.3. Goal and Scope Definition

The Goal and Scope definition in LCA is complementary to the SSbD scoping analysis, in considering additional information, such as functional unit and system boundaries, which may be needed to perform the ESA. For further guidance regarding the SSbD scoping analysis, please consult Section 3.

5.3.1. Functional Unit

The Functional Unit (FU) may change along the innovation process, as increasing knowledge of the chemical/material under assessment becomes available see (Table 5).

When conducting a screening assessment or a simplified LCA the FU usually reflects the unit mass of the chemical/material (i.e. declared unit). For intermediate and full LCA, the FU defines the qualitative and quantitative aspects of the function(s) and/or service(s) provided by the product being evaluated, including temporal requirements (e.g. duration/ durability). The FU should be defined in accordance with the PEF and general ISO-compliant LCAs (Zampori & Pant, 2019).

5.3.2. System boundary

The system boundary may be defined following the decision tree in Figure 23, depending largely on the maturity of innovation, measured here as technology readiness level (TRL). The definition of “low” or “high” maturity of innovation/TRL is self-assessed during the scoping analysis, according to the particular situation.

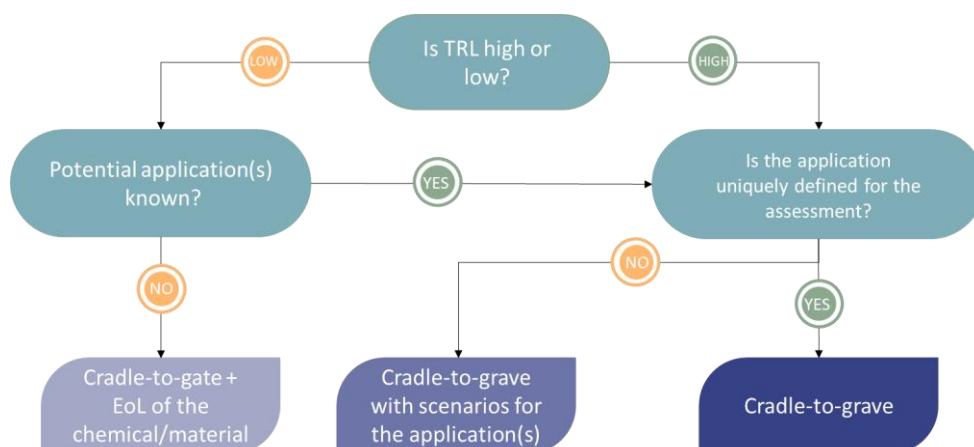
Screening assessments and simplified LCAs could consider **cradle-to-gate** boundaries when potential applications are not yet well defined. End-of-Life (EoL) considerations about the chemical/material should be considered in these simplified assessments, such as the recyclability potential, recycled-content percentage or emissions linked to other EoL strategies or present practices (e.g., incineration and landfill). Where the actual chemical/ material/ product use is unknown, the EoL assessment will be uncertain, by definition, and may be optimistic, to an extent. Nevertheless, such analyses may enable bottlenecks to be anticipated and strategies to deal with them developed, when assessing the circularity improvement potential of the chemical/material.

Once potential applications have been identified, it is possible at this point to consider the entire life cycle (i.e. **cradle-to-grave**) of the chemical/material by considering different scenarios for the different uses and/ or EoL options.

Narrower system boundaries can help to identify hotspots in the production and manufacturing stage of the chemical/ material, also including its precursors, but noting that the results of the assessment will still not be comprehensive, and, as such, may have the potential to be misleading. In addition, once the application sector(s) and product(s) have been identified, a full cradle-to-grave assessment should give the SSbD/ ESA practitioner sufficient information to be able to minimise the risk of environmental burdens shifting between life cycle stages, or between impact types.

When multiple application sectors are envisioned, it is recommended to perform a cradle-to-grave assessment for all possible applications.

Figure 23. Decision tree for defining the system boundaries. The choice of the system boundary depends on the knowledge regarding the final application of the chemical/material under assessment (EoL = End of Life).



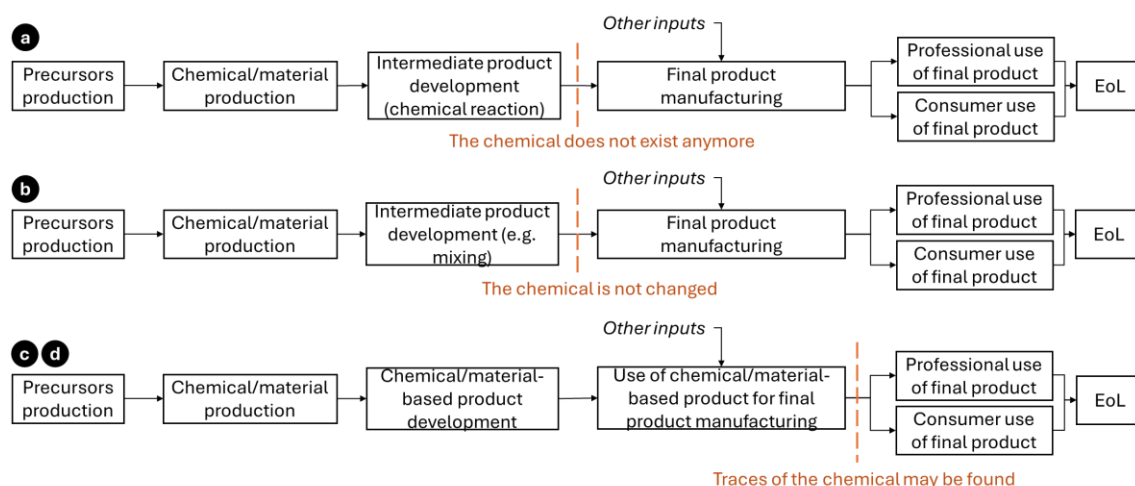
Source: JRC

Depending on the use of a chemical/ material, the structure of its life cycle can be built in different ways, i.e., related to its end-purpose. The following possible end-purposes are considered in Figure 24:

- a chemical/material is used as a reactant in the production of the final product (i.e. it does not exist as a separate chemical substance, post-reaction);
- a chemical/ material is physically combined with other chemicals/ materials in the production of the final product (e.g. via mixing); and
- a chemical/ material is used in the manufacturing of the final product and is not meant to be part of the final product (there is no trace of it in the final product).

Which one applies should be clearly stated in the definition of the system boundary, also in line with the entire SSbD assessment.

Figure 24. Examples of the system boundary for the life cycle of a chemical/material according to its purpose



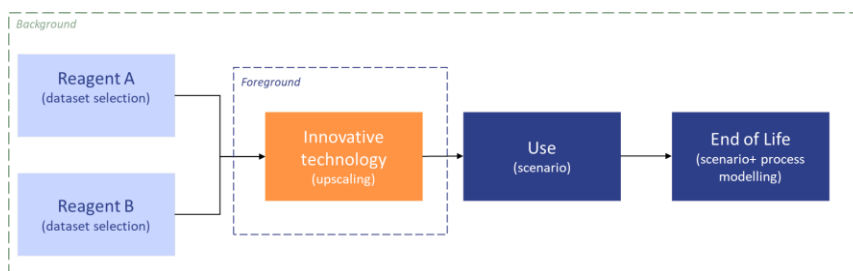
Source: JRC

5.4. Life Cycle Inventory: Data generation and collection

Once the goal and scope (i.e. functional unit and system boundaries) are defined, starting from the SSbD scenario, the data enabling the ESA should be gathered and/ or generated accordingly. From an LCA perspective, the LCI includes all the inputs and emission flows, including energy and material flows, along the entire life cycle of the chemical/material under assessment. Figure 25 shows a general scheme of the life cycle of a chemical/ material, including the upstream and downstream processes in the SSbD system being examined.

From a data point of view, in LCA (and in Social LCA as described in Section 6.1), the system is split into the background and foreground systems. The innovative process is considered as the *foreground system* while the upstream and downstream processes are referred to as the *background system*. The upstream processes include those necessary for the acquisition of the inputs, e.g., reagents and catalysts, as needed for the innovative process being examined. The downstream processes include the set of processes where the newly innovated chemical/ material is used. The last part of the life cycle includes, as usual, the end of life (EoL) management phase of the chemical/ material, which may be described by scenarios when some information is still uncertain or unknown. More specific guidance is provided for the foreground and the background systems in sub-sections 5.4.1 and 5.4.2.

Figure 25. Example of different strategies for data collection and generation for different stages in the life cycle



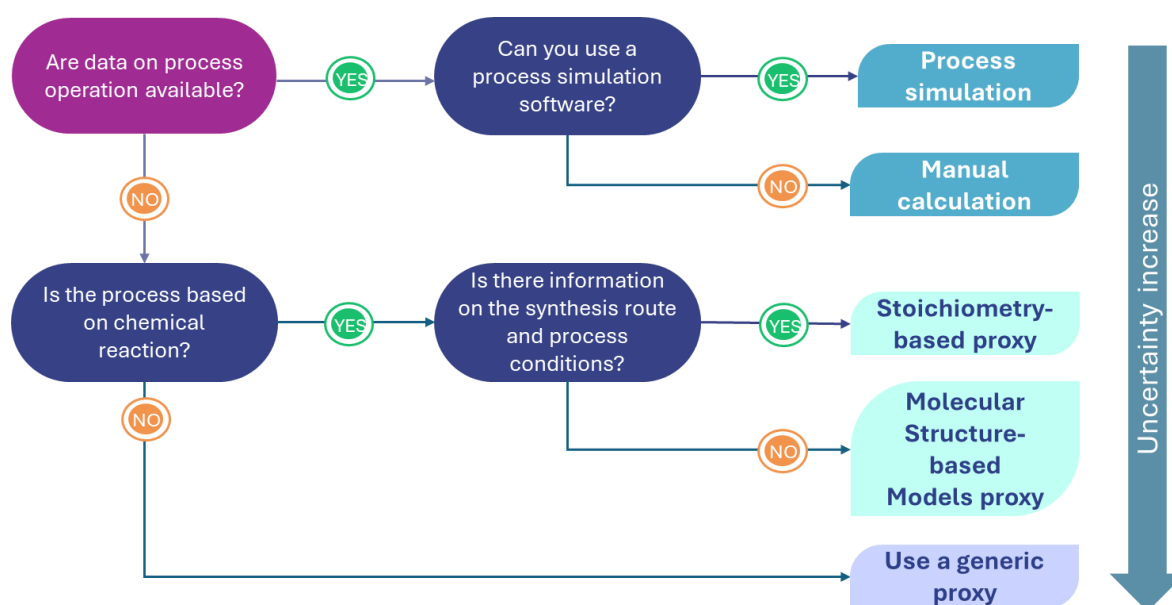
Source: JRC

5.4.1. Foreground system

The LCI of the foreground system is iteratively updated throughout the innovation process. The iteration follows the increasing quality and representativeness of the data.

Compared to a full LCA, in the tiered LCA for a chemical/ material under development, the following two main constraints exist regarding consumption and emission flows: (1) these flows might not be (fully) known; (2) when the flows are collected at laboratory scale, they do not represent the production of the innovative technology at industrial scale (i.e. as the process becomes more commercially viable, there are usually built-in “economies of scale”). Based on these two points and existing studies, a decision tree is proposed in Figure 26 to navigate between the different strategies, to up-scale processes, or to select proxy data, **typically encountered in simplified and intermediate LCAs**.

Figure 26. Decision tree for the selection of the data sources for the data collection and generation. Decision tree adapted from Parvatker & Eckelman, 2019; Tsoy et al., 2020



Source: Own elaboration based on Parvatker & Eckelman, 2019; Tsoy et al., 2020.

According to the scheme above, the following approaches are available, bearing in mind the associated increasing uncertainty:

Process simulation: Software may be used that can simulate chemical and physical processes, based on available engineering estimation methods. They can be utilised to estimate input and output flows to the process, leveraging existing process data to compile an LCI.

Manual calculations: Simpler engineering calculation methods may be used that provide simpler equations or default values for the best-known chemical processes at the laboratory scale (e.g. heating systems), to subsequently scale-up the process to industrial scale (Piccinno et al, 2016). This approach may be useful to derive some key data (e.g. mass and energy balances) of the process that has been developed.

Stoichiometry-based proxy: The stoichiometric relationship of the reagents in a reaction is used to estimate input and output flows of the main raw materials and energy required, creating an ad hoc proxy process. Langhorst et al. (2025) provide an example of an extensive tool built on stoichiometric information.

Molecular structure-based proxy models: Molecular structure models can be applied to generate cradle to gate LCI or to directly predict environmental impacts. These models, such as FineChem2 (Zhang et al. 2024), work on the assumption that similar molecular structures and properties lead to similar environmental impacts. This option should be used carefully, since the basic assumptions are not always valid. The practitioner should check to ensure that the LCIs or LCIAAs generated via these models are consistent with the EF method.

Generic proxy: This type of proxy represents a dataset of chemicals that are assumed to be similar to those comprising the target chemicals. When using a generic proxy, it is important to consider if the similarities are sufficiently close, both in the process and supply-chain of the chosen proxy and the desired chemical/ materials.

Whilst the first three approaches have limitations, they directly utilise information from the specific process under assessment, thus aligning with the definition of foreground. By contrast, the fourth and fifth approaches rely entirely on existing data for a different chemical or material and therefore should be considered as a last resort for estimating foreground processes.

5.4.2. Background system

To model the entire life cycle of a chemical or material being examined, the practitioner should also select appropriate data regarding the background system, also comprising the reagents or catalysts used (Figure 25). Each of these reagents have data associated with them, which can be used in modelling their production. Since primary data might not be available to model the background system, there are some strategies to deal with the modelling of the background according to the processes needed, and to the available information.

Figure 26 can be also used as a guide for deciding on strategies to fill in gaps in the background system. However, it should be noted that some of these procedures, e.g., using **proxy datasets** and Molecular Structure-Based Models (MSBM), may be considered as viable options solely for the modelling of auxiliary chemicals in the life cycle, or for a high uncertainty model, since such models may be too inaccurate for relevant processes, or for a full LCA. Regarding MSBMs, they should be used with caution, since the assumption that the life cycle impacts of a chemical can be inferred from its structure is not always valid.

Wernet, Hellweg and Hungerbühler, 2012 proposed an efficient approach for rapidly screening complex mixtures. They employed a short-cut method (MSBM) to estimate the impact of those components in low concentration, followed by a switch to more accurate proxy data if their estimated impact exceeded a predefined threshold compared to that of the overall mixture.

Background datasets can be found in various LCA databases, but availability may be limited. A fundamental source is the [Global LCA Data Access network \(GLAD\)](#) (UNEP, 2024), which is part of the Life Cycle Initiative hosted by the United Nations Environmental Programme (UNEP). The Life Cycle Initiative acts as a centralised search platform for datasets existing in different LCA databases.

5.4.2.1. End-of-Life

Where the final application of the chemical is **unknown**, modelling must rely on the intrinsic properties of the substance to estimate its environmental behaviour. Key parameters may include – among others – biodegradability, recyclability potential, and the emission or residues generated during incineration or via disposal in landfill. Such an assessment remains inherently partial, as the ultimate environmental impacts at EoL are strongly influenced by the specific application and fate of the substance, for example whether it is encapsulated within a matrix or if it has been chemically transformed into other compounds. Nevertheless, this preliminary evaluation provides essential insights to support the early-stage design and innovation of chemicals/ materials.

When the application is **known**, modelling relies on the disposal scenario(s) of the product in which the chemical/material is included. It is thus important to understand how the related waste flow is managed, together with the associated disposal method(s). For example, consumer products may be disposed of as a municipal solid waste, while ingredients used in a rinse-off cosmetic product are disposed of through wastewater.

The most relevant sources of information on the topic are statistics on waste management. Since waste management is carried out in a different manner in each EU Member State, the most appropriate scenario is often that of the average European scenario, because Europe (as a whole) is most likely the reference market for a chemical or material.

A possible approach for the allocation of impact from waste management is reported in Box 6.

Box 6. Possible approach for the allocation of impacts from waste management

In LCA, there are several approaches to allocate impacts from waste management, when a recycling process is in place among two life cycles. The suggested approach in the PEF method is the so-called **Circular Footprint Formula (CFF)**, which allows the SSbD practitioner to allocate burdens and credits for recycling (and energy recovery), considering differences in quality between the virgin and the recycled material. The demand-offer of the specific market and the effect of substitution of virgin materials (or energy) is also considered (Zampori & Pant, 2019).

The coefficients used in the CFF are constantly updated. However, they are available solely for a limited number of materials, mostly consisting of packaging materials. It is suggested to be cautious in developing *ad hoc* factors for specific cases without robust evidence; furthermore, where there are doubts, it is recommended to conservatively assume that no recycling takes place.

For additional guidance in the interpretation and application of the CFF, see *Damiani et al., 2022*.

5.5. Life Cycle Impact Assessment (LCIA)

When **screening assessment** is applied, this does not involve performing an LCA per se. Rather, it consists of a collection of inventory information, or the calculation of indicators (e.g. process indicators) reflecting key aspects of the innovation pursued (see Sections 5.2 and 5.3). Therefore, the interpretation of the results is performed via the selected indicators (refer to Table 11 of Garmendia Aguirre et al. 2025a). This assessment feeds into the evaluation of subsequent design actions.

In addition, machine learning-based predictions, as well as quantitative relations models such as QSARs, are being developed for the early identification of potential environmental impacts related to a certain molecular structure, such as global warming potential, ozone depletion potential or photochemical potential (such as e.g. Geng et al, 2026; Sgariboldi et al., 2026; Liu et al, 2020). When available, these approaches may be applied carefully in the screening, due to the high

uncertainty and to the missing of elements which are commonly considered in higher tiers of LCIA (e.g. the fate of the molecule in the environmental compartments is often considered in the CFs), which makes the results difficult to be interpreted.

In **simplified LCA**, a narrowed down but well-justified sub-set of the full set of impact categories might be considered to identify hot-spots directly linked to the goal of the innovation. This sub-set can be identified using the information from the screening assessment and may include impact categories that are associated to the aspects and indicators considered in the screening or process-related sustainability assessment (see Section 5.7).

When a **full LCA** is applicable, the SSbD framework recommends the use of the Environmental Footprint (EF) method. The complete set of impact categories considered in the EF is the most accurate way to consider trade-offs along the assessed impacts and to proceed with the interpretation of results stage (See section 5.6). The use of the complete set of impact categories is also suggested where an intermediate LCA is performed. Hence, for convenience and coherence with the method, the use of datasets which utilise the same format as the EF should be favoured, or those for which an adapted version of the LCIA method already exists.

5.6. Interpretation of results and links to the (re)design

In the SSbD context, the interpretation of results and hotspot analysis are key for the tiered and iterative LCA, in order to:

1. Compile the Life Cycle Inventory (LCI), via the collection of primary data, or via more refined strategies fill in gaps, thus reducing uncertainties and improving the quality of the inputs to decision-making; and
2. Prioritise the (re)design of aspects along the life cycle of the chemical/ material that make the highest environmental contributions to the Life Cycle Impact Assessment LCIA (sometimes known as a Contribution Analysis).

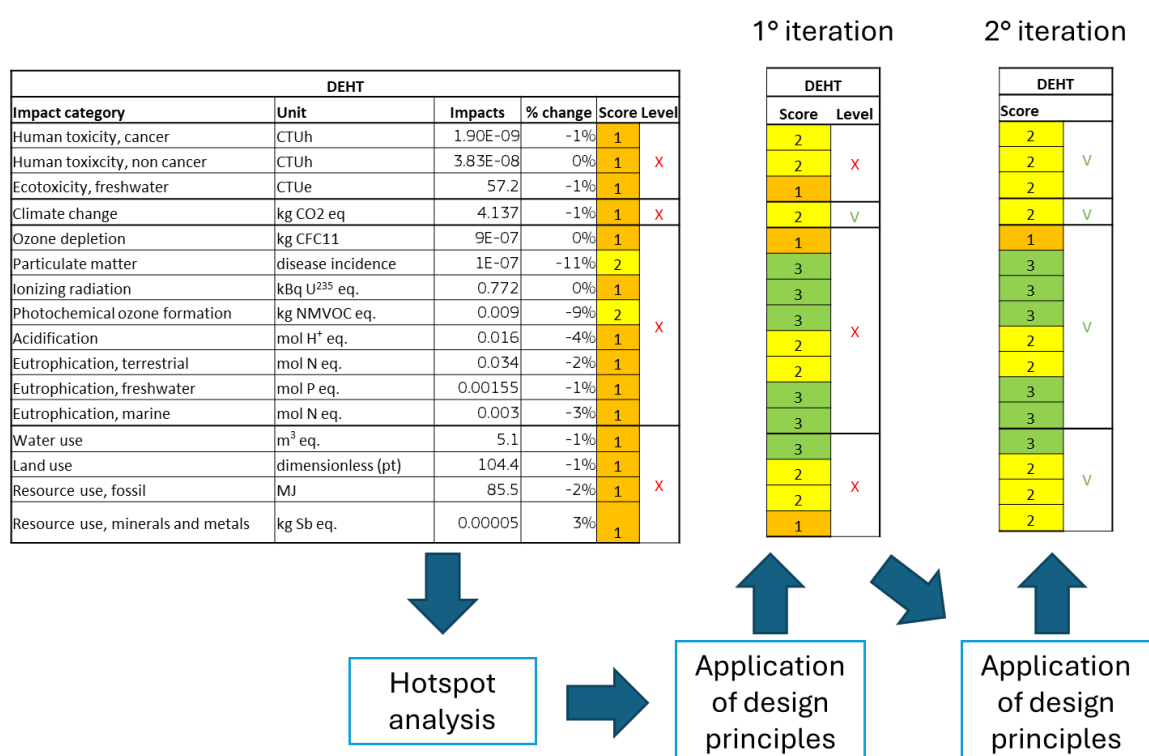
A possible approach to perform the interpretation of the LCA results is described in Figure 26 of Garmendia Aguirre et al, 2025a. In addition, for simplified, intermediate and full LCAs, a detailed procedure for the identification of hotspots is described in Section 6 of the PEF methodology (Zampori & Pant, 2019). This allows the identification of the most relevant life cycle stages, processes, and elementary flows. As intended in the original PEF, this is performed to check the robustness of the LCA model, and also to ensure that important processes are modelled appropriately.

An example of interpretation of results in a tiered ESA is reported in Caldeira et al., 2023 (Figure 18) and in Tosches et al. 2026, where the improvement of environmental performance of a chemical/ material along the innovation process, via the iterative approach of the entire SSbD framework, is illustrated. The example of interpretation of results in a tiered ESA is also reported in Figure 27. Specific guidance is given in Biganzoli et al. 2026 in order to interpret the toxicity-related impact categories and in Abbate et al. 2026a, to support decisions along the innovation when limited data are available and uncertainty is unavoidable (Box 7).

Box 7. How to evaluate and consider the uncertainty within the ESA

Sources of uncertainty, as described through this section, should be systematically considered when interpreting the results of ESA. Depending on the tier, uncertainty can be evaluated in different manners, from qualitative (e.g. based on expert judgement), up to quantitative approaches based on statistical analysis (e.g. Monte Carlo Analysis). Across all tiers, uncertainty should be treated not only as a limitation, but also as an element that helps guide the next iteration of the assessment and redesign, by tracking the source and level of the uncertainty (e.g. making transparent the level of maturity, data sources, assumptions, and data quality used). As such, efforts can be directed towards reducing the type(s) of uncertainty encountered, iteration by iteration.

Figure 27. Iterative (re)design process. Starting from the first assessment, hotspots are identified and prioritised for improvement. In each iteration the assessment is updated until it meets the SSbD requirements



Source: Adapted from Caldeira et al., 2023.

As reported in Figure 27, it is always recommended to the practitioner to report the full sets of LCA results in the evaluation, i.e., separately for each impact category. Nevertheless, when a full LCA is applied, as a second step, an aggregation of the impact assessment results' categories can be considered to facilitate: i) the interpretation and communication of the results, and ii) the application of methodologies to support the decision-making stage (such as MCDA). As further explained in the FAQ (Section 5.8), the 16 environmental impact categories can be grouped in four categories (Toxicity – Climate change – Pollution – Resources). In doing so, the normalisation factors (NFs) and weighting factors (WFs) proposed in the EF method should also be considered. The application of to such an aggregation of impact results should be decided in the scoping analysis, and transparently communicated in the documentation, together with the weighting choices. It should be noted that the aggregation of impact categories can hide possible hotspots and therefore limits the identification of improvements in the different life cycle stages.

5.7. Process-related sustainability

Existent or upcoming technologies supporting the design/redesign of industrial processes can be considered as key enablers to achieve an industrial innovation and transition, with the aim of coupling greater safety and sustainability with economic competitiveness (EC, 2025b).

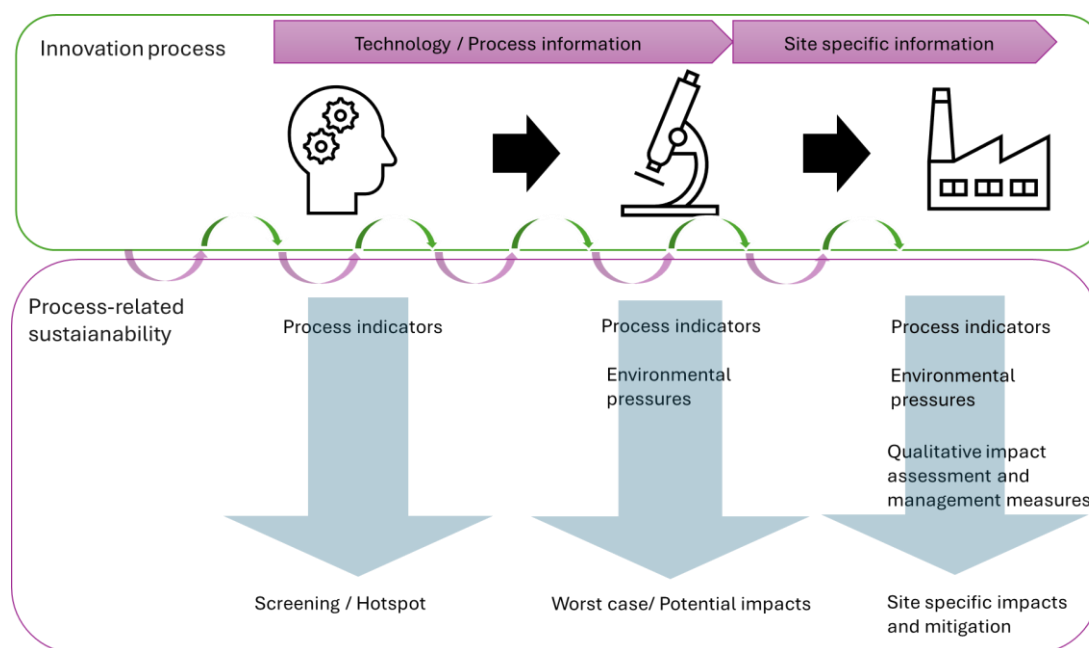
Accordingly, the 2025 revised SSbD framework (Garmendia Aguirre et al., 2025a) introduced two sub-sections in the assessment phase, respectively under the safety and the environmental sustainability assessment, providing a specific focus on industrial process(es) which are under the direct control of the innovators. Aligning with the **precautionary principle**, the main ambition behind this new feature is to identify **possible negative effects and trade-offs to be weighed up in advance**, when scaling up a (new/ improved) technology, including biotechnology, toward its application at industrial scale (EC, 2026b.; EC, 2025d; EC, 2025e).

Process-related sustainability assessment aims to complement process safety by integrating sustainability and ecological aspects that reflect the complexity and the quality of the actual environment close to the plant, moving from a pressure-based approach to that of an impact (or burden)-based perspective (Ayres & Ayres, 2002).

This part of the assessment covers different environmental pressures generated by an industrial plant which are not solely limited to chemicals, but may also include other types of stressors, such as physical and biological pressures, which may be generally related to the environmental compartments of air, water, soil and biota. At the early stage(s) of the innovation, it allows the **prompt identification of possible hotspots**. At later innovation stages, once information became available, the process-related assessment enables the practitioner to consider **specific environmental conditions** related to where the plant is physically located.

A possible application of process-related sustainability assessment along the innovation stages is reported in Figure 28.

Figure 28. Sustainability aspects in a process-related assessment



Source: JRC

The characteristic of this part of the assessment is that it allows the practitioner to consider **one specific life cycle stage of the chemical/ material at a time**, at the location(s) where the industrial process(es) may occur, from the extraction of the required raw materials up to the end-of-life management phase. This gives the possibility to integrate **site-specific considerations, which otherwise could be missed**. Indeed, this approach differs to that of a classic LCA study, where, in the latter, the output of the impact assessment is often considered in terms of “potential impacts” (Sluser et al., 2022), especially for those which refer to mid-point level indicators, such as the EF methods (EC, 2021a).

5.7.1. Tiered approach for process-related sustainability

The approach outlined below takes inspiration from the various types of environmental legislation that might apply to the development of the specific process, including environmental permitting schemes such as IED (EU, 2024a.), EIA (EU, 20014), waste (EU, 2008b.), wastewater (EU, 2024b) and landfill (EU, 2018). In addition, the approach also refers to pollution control and assessment schemes for environmental quality such as air (EU, 2024c), water (EU, 2000; EU, 2008c; EU 2006b) and soil (EU, 2025) and protection (for example, the specific habitat (EU, 1992; EU, 2009)). As such, a tiered approach for carrying out process-related sustainability assessment is described below, proposing indicators and possible criteria.

The tiered approach for process-related sustainability assessment implies moving from low TRL (with consequently a simplified SSbD scenario) to high TRL, and consequently a full process sustainability assessment. At low TRL, data availability is limited and only a preliminary assessment is possible, based on process indicators; uncertainty is high. Progressively, moving towards a medium TRL with an intermediate SSbD scenario, environmental pressure indicators can be considered together with more accurate process indicators, allowing a more sophisticated assessment to be made, with medium levels of uncertainty. Finally, at high TRL, with a full SSbD scenario, site-specific information may allow one to reduce the uncertainty of the previous indicators and to carry out an investigation into the environmental state of the site, with an associated qualitative to semi-quantitative environmental impact assessment.

The results of the assessment can be displayed in the dashboard proposed in the SSbD framework (Figure 35, page. 91) to either compare different (existing) processes (for example applying different technologies), or to evaluate the environmental sustainability performance of a new process.

Table 6 provides an overview of the flexible and tiered approach which is suggested for the process-related sustainability assessment. Therein, the different possible sources of information are reported, while Annex E of this SSbD guidance document includes a list of possible indicators and index that could be chosen, depending on the specificity of the process(es) being addressed. Indicators that are useful at a given stage of the innovation may be reused and adapted at later stages. For example, a material intensity index could be calculated at a very preliminary phase using theoretical data and estimations for a chemical reaction.

Finally, section 5.7.2 gives a possible example, where process-related assessment has been applied to a medium/ high TRL technique/ technology.

Table 6. Tiered approach in the context of process-related assessment

<i>Low/ Simplified</i>	<u>Process indicators:</u> Table 11 of <i>Garmendia Aguirre et al, 2025a</i> (aligned with a screening LCA) <u>Criteria:</u> Based on generic range or theoretical values If criteria are not met, refine the assessment <u>Source of information:</u> Process information	<u>Environmental pressure indicators:</u> Screening of possible emissions to air, water, soil (not solely limited to chemicals, but also including physical and biological agents), also considering if these emissions are accounted in the most relevant impact categories of the EF. <u>Criteria:</u> Yes/no presence in regulatory lists If criteria are not met (i.e., a regulated pollutant is potentially emitted) flag this emission for further investigation <u>Source of information:</u> Process information, technical annexes of environmental regulations.
<i>Medium/ Intermediate</i>	<u>Process indicators – refinement:</u> refinement of the list of indicators <u>Criteria:</u> Possible to refine based on a specific range If criteria are not met, consider a redesign of the process <u>Source of information:</u> Process information, BAT reference documents Damari et al., 2025	<u>Environmental pressure indicators – refinement:</u> Estimate of emission to air, water, soil (not solely limited to chemicals, but also including physical and biological agents) <u>Criteria:</u> Yes/no presence in regulatory lists and possible exceed of the thresholds If criteria are not met, refine the assessment <u>Source of information:</u> Process information, technical annexes of environmental regulations. BAT reference documents (EC, 2026b) (see Associated Emissions Level/ Associated Environmental Performance Level AEP/AEPL values where existing)

High/ Full	<u>Process indicators – refinement:</u> Refinement of the list of indicators	<u>Environmental pressure indicators – refinement:</u> Estimation of emission to air, water, soil (<u>not limited to chemicals, including also physical and biological agents</u>) or measurements based on pilot plant/experimental data	<u>Environment state indicators:</u> Chemical and biological indicators to estimate the ecological status of the environmental compartments. The presence of sensitive/critical environmental area (es: Natura 2000 (EEA, 2026a)) and vulnerable species should be considered. <u>Environmental impact assessment:</u> Qualitative to semi-quantitative impact assessment of the related to the environmental site-specific pressures of the process, possibly from an integrated perspective. Different methods can be applied to qualitatively assess the negative impacts in the different environmental compartments such as air, water, soil, biota and their interaction (EVS Institute Environmental Studies, 2026) from ecosystem and landscape perspective. For new processes, a reference should be identified as background to evaluate the impacts on the environmental status of the site. It is possible to qualitatively describe how the impact will evolve from a temporal perspective (from the construction, production and decommissioning phases), taking into consideration ecological attributes of the specific environment such as the resistance and the resilience of the ecosystem.
	<u>Criteria:</u> Possible to refine, based on a specific range If criteria are not met, considering the redesign of the process	<u>Criteria:</u> Yes/no exceeding regulatory thresholds If criteria are not met: - considering Risk Management Measures (from Best Available Techniques), - considering the redesign of the process	<u>Criteria:</u> Yes/no negative environmental impacts (integrated) as consequence of environmental pressures generated by the process. In case of negative impacts, the assessment could be further refined by applying semi-quantitative quality index, using scoring systems (e.g., varying from good to poor or 0-10 scales), enabling the ranking, prioritisation, and rapid screening of environmental impacts. Where negative impacts are possible, mitigation measures should be considered and, as a last option, a different location for the plant (if it is a new plant) should be taken into consideration.
	<u>Source of information:</u> Process information	<u>Source of information:</u> Primary data (Inventory) of processes inputs and outputs, annexes of existing regulations, BAT reference documents (EC, 2026c) (see AEL/AEPL values where existing)	<u>Source of information:</u> Primary data (Inventory) of processes inputs and outputs (EEA, 2026b; EEA, 2026c; WISE, 2025; EC, 2026d; Arena, 2026; Copernicus, 2026), IPCHEM (EC, 2026e) and GIS databases (ArcGIS, 2026; RTWilson, 2026)

Source: JRC

5.7.2. Example of a tiered approach in process-related sustainability assessment

Example on membrane manufacturing

If one considers again the process of membrane manufacturing mentioned in section 5.2.1, the following are pertinent. For this type of process, energy and water use are relevant environmental aspects, together with the type and amount of raw materials used to manufacture the membrane. Hence, these are aspects which can be examined more thoroughly via process-related sustainability compared to the overall sustainability assessment.

LOW innovation maturity/ TRL. At the beginning of the design, the goal is to achieve an appropriate functionality of a base polymer, to remove a target pollutant. Since the development is still theoretical or limited to laboratory experiments related to molecular design, the practitioner can concentrate his/ her attention on the different types of precursors used for the functionality of the membrane and their potential pollutant emissions. Since the design is still preliminary (laboratory phase), a quantitative evaluation is not necessary, and a simple checklist could be sufficient.

Indicator: Presence of regulated substances (pollutants, hazardous chemicals, etc) among the raw materials.

INTERMEDIATE innovation maturity/TRL. At the intermediate level, parameters related to the manufacturing process become available through more extensive experiments or more accurate calculations. Hence, the practitioner may decide to set criteria based on energy consumption and water use. Moreover, starting from the checklist of potential emissions developed at early stages, they build an indicator for the emissions expected (or measured at the pilot plant) from the process, related to regulatory limits for the same substances. This represents a refinement of the previous indicator, which now takes into account the real raw materials used and realistic data.

In this way an Industrial Emission Index (IEI) can be built in the following way:

$$\text{IEI: } \max \left(\frac{C_i}{ELV_i} \right),$$

where

C_i is the concentration of chemical i with the regulatory limit ELV_i

In this way, it is possible to have a qualitative evaluation of the distance from a target (regulatory), with a qualitative scale such as that the one in the following table:

Interpretation:

IEI	Status
≤ 80	Good
80–100	Warning
> 100	Non-compliant

Indicators: Energy consumption (MJ/kg membrane), Water use (kg/kg membrane), Industrial Emission index

HIGH innovation maturity/ TRL. At high innovation maturity/TRL, the process has already been largely decided upon, and fewer adjustment are needed to operationalise the process at industrial scale. For this reason, a more complete description of the environmental impacts and pressures on the environment can be made, introducing also site-specific considerations.

For example, for impacts, a “gate-to-gate” LCA can be useful, to incorporate different data from the process (e.g. emissions, raw materials and waste) into a unified metric which can also be monitored in time for continuous improvement. Moreover, this gate-to-gate assessment will be complemented by the full LCA or cradle-to-gate LCA performed for the overarching sustainability (see Section 5). A subset of environmental impact categories can be chosen, as relevant for the specific type of process, such as the manufacturing of the membrane.

In this case, climate change, water use and fossil resource use may be more relevant.

At high innovation maturity/ TRL, the practitioner can take into consideration the real geographical, ecological and geological location of the plant to assess local impacts of the process. For example, it should be estimated (if not already possible to measure) the actual water source requirements for the manufacturing of the membrane, its quality after the process (in terms of physio-chemical and also biological parameters) and the efficiency of wastewater treatment, and how these steps could potentially affect aquatic species and habitat close to the plant. The ecological status of the environmental compartment(s) involved, for example the groundwater basin and the surface fresh-water body, should be considered to estimate the impacts.

Indicators: refinement of the industrial emission index, e.g. based on more accurate/ measured data, chemical and ecological quality indicators for surface water (and possibly groundwater).

5.8. FAQs for the implementation of ESA

How do the scoping analysis and the related SSbD scenario(s) inform and tailor the ESA?

The scoping helps to define the system under study, based on the goal and maturity of the innovation. Hence, it does not provide elements to inform decision making but instead frames the assessment itself. Outcomes from the scoping analysis inform the ESA in different ways. For example: when considering the goal and scope, the LCI should be based on the definition of the SSbD system, the actors involved and the availability of information. Similarly, when prioritising the sustainability elements to be considered in the tiered ESA (i.e. the screening and simplified LCA), this also needs to consider what is the goal and the objective of the innovation and which redesign is applied.

What is meant by the terms “reference” and “benchmark”?

The benchmark represents the basis for comparison for the products with the same function. This is required by ISO 14040 and 14044 and by the PEF methodology (ISO, 2006, 2018; Zampori & Pant, 2019). The representative product is the average product for the definition of the benchmark. The reference chemicals and application can be used as a reference for the innovation process, keeping in mind that the two systems have to be compared based on the same functionality. Further explanation is provided in Section 5.25.2

The suppliers do not want to provide data. How can I deal with this?

In principle, there are databases that allow one to fill in any data gaps in LCA. If not, literature reviews can be performed to enable the practitioner to gather data and model a process. The last choice is to use proxies, which are processes of other chemicals/ materials which are similar to the one under

assessment, for selected reasons. However, LCA for chemicals/ materials requires higher quality data regarding upstream processes. Whenever possible, communication with suppliers is the best choice. This can be mutually beneficial. If this is not possible, sensitivity analyses are crucial to identify the possible parameters and aspects that affect the results the most.

Should I follow the Product Environmental Footprint (PEF) methodology?

The Product Environmental Footprint (PEF) is the suggested methodology by the EC to perform the LCA (European Commission, 2021a). The PEF builds on existing approaches and international standards. The rules provided in the PEF method enable practitioners to conduct PEF studies that are more reproducible, comparable, and verifiable, compared to existing alternative approaches. Nevertheless, it might be challenging to perform such a study at the early stages of innovation. Hence, a simplified version of the PEF study without the increasing complexity and completeness of the modelling can be initially performed, then the data and the modelling are progressively refined along the innovation, following the increasing knowledge about the chemical/material.

Is it possible to perform a carbon footprint instead of assessing all the impact categories?

The carbon footprint quantifies the greenhouse gases emissions of a product along its entire life cycle. In the context of the SSbD framework, the carbon footprint should be assessed for the chemical/ material under assessment. However, the quantification of the carbon footprint is narrowed down to only one impact category (i.e., climate change), with a consequent incomplete assessment. The SSbD ESA aims to provide a holistic assessment of the environmental impact which

therefore does not solely consider climate change. In this way, trade-offs between impacts and hot spots can be identified. In addition, the effort dedicated to the input data collection and generation is needed, regardless of the number of impact categories considered. Nevertheless, discussions and interpretations for all the impact categories need to be made to identify hotspots and the quality of the results, and to prioritise iterative modelling needs.

What are the Planetary Boundaries (PBs)?

The Planetary Boundaries framework assesses the limit within which humanity and ecosystems can develop and thrive for generations. There are currently nine planetary boundaries assessed, of which six are currently transgressed. Crossing boundaries increases the risk of large-scale abrupt or irreversible environmental changes that can undermine human development. More information and updates on the topic can be found at the Stockholm Resilience Centre website (Diamond et al., 2015; Stockholm Resilience Centre, 2024).

How are the different impact categories of the Environmental Footprint method linked to the Planetary Boundaries (PBs)?

The environmental impacts measured with LCA have been linked to the Planetary Boundaries through a cause-effect link, where possible. This procedure allows one to calculate a threshold for the so-called “safe zone” of each impact category. The details of this procedure are available in Sala *et al.*, 2020.

How can LCA results be aggregated to obtain a single weighted Sustainability score in SSbD?

Once the LCA results are obtained, the comparative assessment requires that the

reference is assigned the score of “1” for each impact category. According to the scoring system for environmental sustainability assessment shown in Table 50 of the case study (Caldeira et al., 2023), all the alternatives are compared to the reference. Once all the scores have been assigned, the impact categories can be aggregated to aid the input to decision-making and the identification of hotspots. Caldeira et al., 2022a propose an aggregation at the level of four separate groups, to determine the level for each impact category group:

- Toxicity: Human toxicity – cancer, human toxicity – non cancer, and Ecotoxicity – freshwater
- Climate change
- Pollution: aggregating Ozone depletion, particulate matter, Ionizing radiation – Human health, Photochemical ozone formation – human health, Acidification, Eutrophication – terrestrial, Eutrophication – freshwater, and Eutrophication – marine
- Resources: water use, land use, resource use – fossil, and resource use – minerals and metal.

What is the added value of the process-related sustainability assessment, within the ESA?

Process-related sustainability introduces a different angle to the LCA-based environmental sustainability assessment, especially in high TRLs when site-specific information might be available (more of a “source-pathway-receptor” environmental risk assessment approach, as espoused in the environmental sustainability part of the Seveso Directive). Potentially, this approach would allow also for the integration of socio-economic aspects at a local and site level, for instance related to the health and safety performances at company level.

6. Socio-economic sustainability assessment

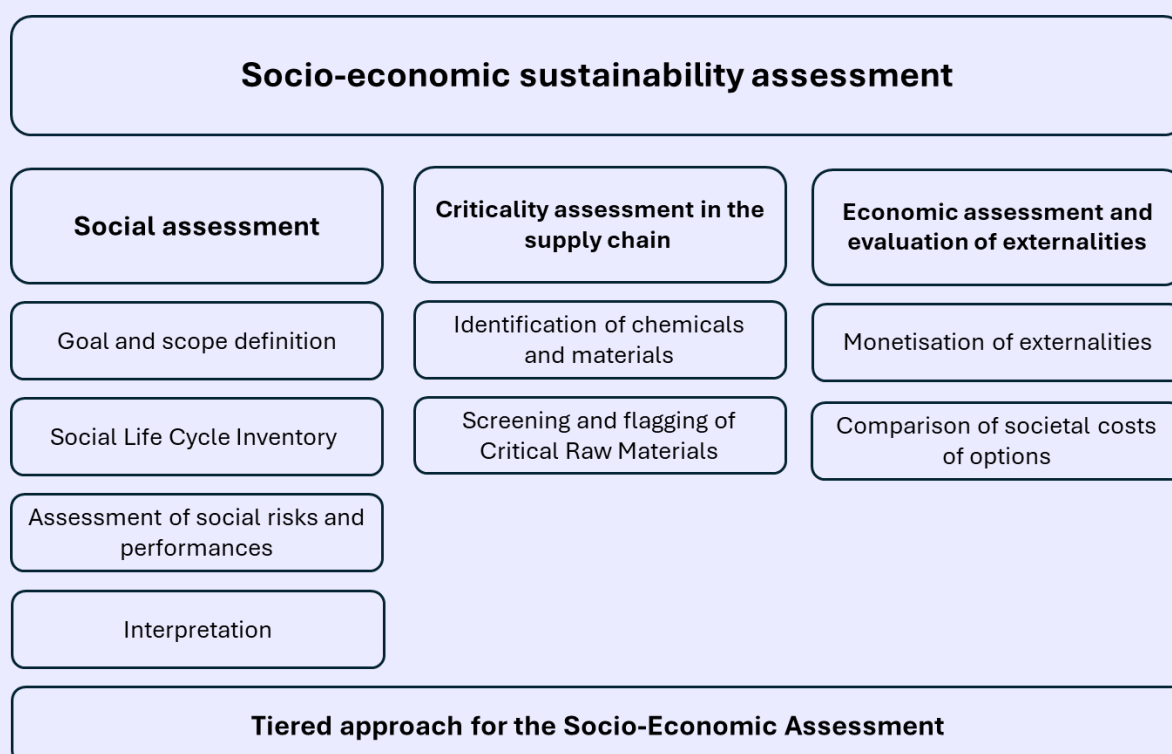
AIM OF THE SECTION:

Socio-economic assessment has now been added in the 2026 EC SSbD Recommendation as an integral part of SSbD, rather than being optional, as previously. Approaches to undertake socio-economic assessment have been explored in previous JRC publications, e.g. in the review of frameworks, in the first SSbD framework (Caldeira et al., 2022a), in the related case study report (Caldeira et al., 2023) and in the first methodological guidance (Abbate et al., 2024). The aim of this section is to provide updated guidance on undertaking socio-economic assessment, aligning with the revised SSbD Framework.

The figure below illustrates the main elements of the guidance for this phase, which is based on the following methodological approaches:

- **Social assessment:** identification and assessment of social risks and performances along the life cycle using a reference scale method.
- **Critical Raw Materials (CRMs)** identification: analysis of life cycle inventories and flagging the presence of CRMs.
- Monetisation of externalities and comparison of **societal life cycle costs** (only for applications at high maturity levels and for comparison of alternatives).

Figure 29. Structure of the socio-economic sustainability assessment section



Source: JRC

6.1. Social assessment

Social Life Cycle Assessment (S-LCA) is a methodology to assess the social impacts of products and services across their life cycle (e.g. from extraction of raw material to the end-of-life phase, e.g. disposal). In the context of the SSbD, a simplified S-LCA is proposed as a method to capture potential negative and positive socio-economic impacts of chemicals and materials, along the innovation process and considering their life cycle.

The methodology of S-LCA mirrors that of Environmental Life Cycle Assessment (LCA) with four key phases: defining the goal and scope, making an inventory of life cycle data, assessing impacts, and interpreting results. However, S-LCA diverges from environmental LCA in its focus on stakeholder identification, the selection of impact categories, and in the evaluation of both negative and positive impacts (environmental LCA only considers negative impacts).

Methodological guidance for S-LCA is provided by the UNEP Guidance (UNEP, 2020) and the ISO standard “Environmental management. Principles and framework for social life cycle assessment” was published (ISO, 2024). This specifies two possible impact assessment approaches: the Social Life Cycle Impact Assessment and the **Reference Scale Assessment**, which is the suggested method in the context of SSbD (see sections 6.1.3.).

Possible applications of the S-LCA methodology in the context of the SSbD include (Munares Sánchez et al., 2026):

- Comprehensive social impact assessment across entire product life cycles
- Comparative analysis of alternative products against baselines
- Evaluation of different supply chains or technological development for the same product
- Identification of social risks or hotspots within the supply chains to detect improvement opportunities
- Stakeholders' perspectives integration and performance optimisation
- Support for early-stage decision making during product development and innovation processes.

This section offers practical guidance on the key steps of the methodology, i.e. the goal and scope definition (Section 6.1.1), social and life cycle inventory (Section 6.1.2), the social risk and performance assessment (Section 6.1.3) and interpretation (Section 6.1.4).

6.1.1. Goal and scope definition

In S-LCA, the goal and scope phase requires the definition of several aspects, i.e.: the intended application of the study, the intended target audience, the reason for conducting the study, the functional unit, the life cycle stages, and processes included in the study, the system boundaries. In an SSbD study, these aspects are addressed in the **scoping analysis**, through the three phases of system definition, intended innovation/(re)design definition, and engagement with the actors along the life cycle.

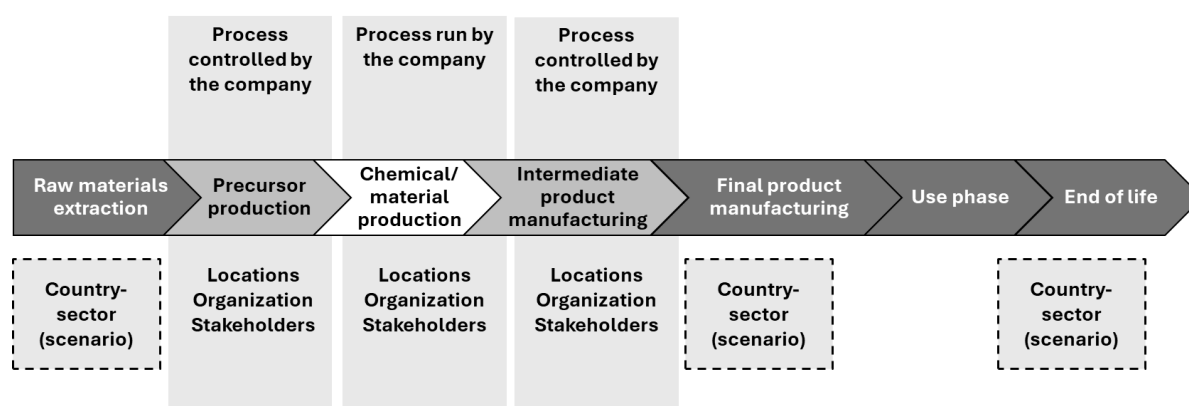
At the same time, the goal and scope definition within the social assessment aligns and build on the environmental sustainability assessment phase, especially in the **system boundary** definition. As for the LCA, a simplified cradle-to-gate assessment may be used when applications are not yet defined, but as soon as use and end-of-life scenarios can be specified, a cradle-to-grave, scenario-

based approach is strongly recommended to capture social risks and impacts across all life-cycle stages and avoid burden shifting between value-chain actors and phases.

For the social assessment, the goal and scope phase should be complemented by the following tasks:

- **Defining the level of detail** appropriate to the maturity of the innovation (screening or full quantitative assessment).
- **Identifying the organisations** involved in the different parts of the SSbD system, their role (e.g. supplier, distributor), location and the level of relationship with the organisation, building on the scoping analysis, which includes the identification of key actors in the life cycle.
- **Selecting potential country-sector combinations** for the steps with unknown organisations, to allow the use of secondary data at country-sector level. Scenarios testing different countries can be applied, aligning with the assumptions and scenarios outlined (Figure 30).
- **Assessment of relevant indicators:** the revised SSbD framework provides a list of indicators that are recommended for their application in the SSbD context, as they allow to detect hotspots in terms of social fairness and potential competitiveness opportunities. These indicators are listed in Table 7 and refer to five categories of negative or positive impacts:
 - Human rights
 - Working conditions and quality of jobs
 - Health and safety
 - Contribution to economic development
 - Skills and technology innovation potential.

Figure 30. Example of a generic system boundary for the social assessment



Source: JRC

Notably, the first three categories refer to fundamental principles and rights at work listed in the ILO Declaration (ILO, 2022) and therefore represent a **core set of categories** for assessing the social sustainability of a chemical/material, considering the whole life cycle. The categories “contribution to economic development” and “skills and technology innovation potential”, instead, aim at capturing potential benefits of developing a value chain related to a chemical/material, and the related indicators suggested in Table 7 can be customised and complemented. The **health and safety** indicators (related to presence of safety measures; accidents at work and safe and healthy

living conditions) complement the safety assessment of the SSbD and can be part of the process-level sustainability assessment described in section 5.6.

Table 7 Listing of socio-economic aspects, categories and indicators. Categories with (*) are related to the ILO Declaration on Fundamental Principles and Rights at Work and represent a core set of essential categories to perform a social sustainability assessment.

Socio-economic aspect	Socio-economic category	Examples of indicators
Human rights*	Risk of child labour in the supply chain	Proportion of children engaged in economic activity (%)
	Risk of forced labour in the supply chain	Global Slavery Index Goods produced by forced labour
Working conditions and quality of jobs*	Fair salary	Average monthly earnings of employees by sex and economic activity
	Working time	Mean weekly hours worked per employed person by sex and economic activity
	Equal opportunity and discrimination	Gender wage gap (%) Proportion of women in senior and middle management positions (%)
	Freedom of association and collective bargaining	Level of national compliance with labour rights (freedom of association and collective bargaining)
Health and safety*	Presence of safety measures	Preventive measures and emergency protocols exist regarding: i) accidents and injuries, ii) pesticide and chemical exposure
	Accidents at work	Fatal/non-fatal occupational injuries per 100'000 work-
	Safe and healthy living conditions	Organisation efforts to strengthen community health (e.g. through shared community access to organisation health resources)
Contribution to economic development	Contribution economic development	Contribution of the product/service/organisation to economic progress (e.g. annual growth rate of real GDP per employed person)
	Creation of knowledge-intensive employment	Average proportion of skilled workers, out of all workers (%) <u>Knowledge intensive jobs (% high-skilled employees</u>
Skills and technology innovation potential	Technology potential	Involvement in technology transfer program Projects partnerships in research and development <u>Investments in technology development/ technology</u>
	Skill shortages risk	Ratio of training investment per employee vs. industry benchmarks. Qualitative assessment of the extent to which the com-

Source: JRC

Additional aspects that could be considered refer to the role of a chemical/material for society, e.g. in terms of contribution to public health and societal needs and impacts that account for both positive and negative aspects related to the usage of a chemical/material (as suggested in Tunali et al. (2025) in the case of biocides).

Positive impacts in S-LCA can be defined as: positive social performance going beyond business as usual (type A); positive social impact through presence (product or company existence) (type B); positive social impact through product utility (Type C). While types A and B can be assessed quantitatively with indicators related to e.g. provision of training and job creation, the quantitative

assessment of type C impacts presents more challenges due to lack of methodological development (Di Cesare et al., 2018).

Moreover, the selection of indicators may be validated and refined based on stakeholders' consultation, expert judgement and context-specific considerations.

6.1.2. Social Life Cycle Inventory

The Social Life Cycle Inventory (S-LCI) consists of collecting data and performing all the calculations needed to quantify and qualify inputs and outputs of a product system. The process of conducting an S-LCI is iterative, and data can be integrated as more is learned about the system.

As in the environmental assessment, **background** and **foreground** systems can be defined in the social assessment, using mainly primary data for the phases in the foreground system and secondary data for those the background system. For the social assessment, both **quantitative** and **qualitative** data can be used; in both cases the use of reference scales allows the interpretation of the results aligned with the ESA scoring system. Overall, data and information may be classified in these two main groups:

- **Primary data** (company or site-specific data): These data describe the behaviour of the organisation(s) involved and are usually used to measure the **social performances** of those processes under the direct/indirect control of the company conducting the assessment. The primary data should be collected to reflect company-specific behaviour, measured only by referring to specific and real situations, capturing both negative and positive aspects. An example of social performance for the social topic "discrimination and equal opportunities" is whether the organisation has formal policies in place on equal opportunities and what these consist of.
- **Secondary or generic data** (sector or country level data) consist of information from statistics and databases that describe the likelihood that a certain social topic is relevant, and are used for assessing **social risks**, especially in the background processes (i.e. not directly controlled by the organisation performing the study). These types of data can be used for both social risk assessment (or hotspot analysis) and for complementing information on the remote parts of the life cycle in a performance assessment when no direct information or data are available. For example, if it is not possible to know the rate of accidents at work in an upstream phase of the supply chain, it is possible to use country-sector estimates from the available databases (see Zanchi et al., 2024).

Possible secondary data sources that can be used for the social assessment are available in Annex F. Both for primary and secondary data, where there is a lack of data, missing parts of data or other limitations, these must be clearly documented, as this will help the interpretation of the results.

6.1.3. Assessment of social risks and performances

The **Reference Scale Assessment** (RSA), as defined in ISO 14075:2024, aims at assessing the social performance of the product system based on specific reference scales and associated Performance Reference Points (PRP). The implementation of the reference scale consists in the conversion of S-LCI results to a score value according to an established pre-determined reference scale for each impact category or indicator. The reference scale should be defined according to international and/or national norms, where available, or according to best practices.

These reference scales can be based on quantitative values (usually translated in levels of risk, as in Table 8 or qualitative information, that can be translated in performance levels (as in examples in Annex F). These scales should correspond to levels of risk or performance related to known intervals and thresholds.

For the **performance assessment**, an example of a reference scale is provided by Pihkola et al. (2022). It consists of a five-levels scoring system, from -2 to +2 where level +2 corresponds to the ideal performance, while the worst performance (-2) corresponds to non-compliance or no action taken. A detailed description of the reference scales proposed is given in Zanchi et al., (2024).

Concerning the **social risk assessment**, the Product Social Impact Life Cycle Assessment database (PSILCA) database provides risk levels for a set of social indicators (Loubert et al., 2023) grouped into 25 social subcategories (social topics). Risk levels range from "very low risk" to "very high risk" with intermediate levels called low, medium, high and no risk. The level of risk is attributed to the indicator based on the social raw value and the specific reference scale.

An example of reference scale for the indicator "Rate of fatal accidents at workplace" is presented in Table 8.

Table 8. Reference scale used to assess the indicator "fatal accidents at work"

Rate of fatal accidents at workplace		
Unit: # per 100k employees		
Indicator value	Social Risk level	Performance Reference Points
$0 \leq y < 7.5$	Very low risk	4
$7.5 \leq y < 15$	Low risk	3
$15 \leq y < 25$	Medium risk	2
$25 \leq y < 40$	High risk	1
$40 \leq y$	Very high risk	0

Source: Caldeira et al., 2023, adapted from the reference scale available in PSILCA.

The combination of primary and secondary data in the socio-economic assessment requires careful interpretation. Primary data generally describe the actual social performance of a specific company or site, while secondary data (e.g. country–sector databases) provide estimates of potential social risks in the broader supply chain context. As highlighted in Zanchi et al. (2024), it is recommended to perform a parallel interpretation of results, where risk-based secondary data and performance-based primary data are reported side by side rather than merged into a single score.

Within the SSbD social assessment, **benchmarking** needs to be defined carefully, especially for innovative solutions with low levels of innovation maturity. The choice of the baseline can refer to the current conventional supply chain, to a sectoral or country–sector average, or a best-performing (e.g. certified or low-risk) sourcing model. This choice strongly influences the interpretation of results.

For early-stage innovations, many value chain configurations are still hypothetical, and the assessment can only examine country–sector combinations and different value chains possibilities in an iterative way and at a general level, enabling early-stage social impact consideration despite the high uncertainty.

In social assessment, benchmarking should therefore be iterative and scenario-based, with transparent assumptions on sourcing and geography. This allows tracking progress over time while and flagging potential high-risk processes along the value chain, requiring further investigation.

The recommended interpretation level in SSbD is at the indicator level, but, where useful, **aggregation** up to socio-economic aspects (e.g. human rights, working conditions, health and safety) is possible. Aggregation across broader dimensions (e.g. social fairness or competitiveness) may be used only as an optional communication and benchmarking support tool and should not replace the interpretation of individual indicators and identified hotspots. Where aggregation is performed, the methodology, assumptions and weighting choices should be transparently reported. In the absence of internationally harmonised weighting factors for S-LCA, if weighting is applied, stakeholder-informed approaches and sensitivity analysis are recommended, and the rationale should be documented.

In general, compensation (i.e., overall net summing up) should be avoided between positive and negative impacts within or across different social topics and stakeholder groups. For example, a negative performance on child labour by one supply chain actor should not be compensated in an aggregation score by positive performance on, e.g. contribution to economic development .

6.1.4. Interpretation

The results of the social assessment should be interpreted according to the goal and scope of the study, taking into account the limitations due to data quality and data gaps. Unlike the other SSbD phases, the social assessment part aims at raising awareness on potential social risks and supply chain improvements rather than providing quantitative impact assessment results. In this respect, the interpretation should focus on identifying significant issues, i.e. socio-economic categories and/or supply chain stages that deserve attention and further investigation. These outcomes could support the development of risk mitigation strategies and contribute to the development of regulatory obligations in terms of sustainability reporting (EU, 2022) and due diligence (EU, 2024d) as described in the first methodological guidance (Abbate et al., 2024).

The interpretation phase includes also the evaluation of the methodology and results for completeness, sensitivity and consistency, as described in the ISO 14075:2024.

6.2. Criticality assessment in the supply chain

Within the SSbD framework, the assessment of Critical Raw Materials (CRMs) contributes to identifying supply chain vulnerabilities along the life cycle of the chemical/material.

According to the EU methodology (see, e.g. Grohol & Veeh, 2023), CRMs are raw materials with high economic importance for the EU and a high supply risk, often due to concentrated sourcing and limited substitutability. The EU list of CRMs is updated periodically; the 2023 assessment identifies 30 critical raw materials.

In the context of SSbD, tracing the presence of CRMs in the supply chain supports the socio-economic sustainability assessment by increasing awareness of potential material dependencies, exposure to supply disruption and recovery opportunities. When (re)designing chemicals, materials, processes or products, the SSbD practitioner should therefore verify whether the innovation increases, maintains or reduces the reliance on CRMs across the life cycle.

A broader analysis of supply chain vulnerabilities can complement the CRM assessments with qualitative information concerning additional potential risk factors (Box 8).

Box 8. Assessing broader supply chain vulnerabilities beyond Critical Raw Materials

While the revised SSbD framework currently includes the identification and flagging of Critical Raw Materials (CRMs) along the life cycle, supply chain resilience depends on a wider set of structural and systemic factors. Recent literature on economic security and supply chain resilience highlights that vulnerabilities can arise from a combination of resource dependencies, geopolitical dynamics, environmental factors, and systemic interdependencies across global value chains (OECD, 2025b; OECD, 2025c).

Supply chain vulnerability can be understood as the sensitivity of a value chain to internal and external disturbances arising from design choices, structural dependencies, and external shocks (Sharma et al., 2023).

To complement CRM flagging, the analysis of supply chain vulnerabilities in SSbD applications can therefore include a qualitative screening of additional risk factors. This broader perspective is consistent with recent research showing that vulnerabilities associated with innovative technologies span economic, environmental, societal, and governance dimensions. The analysis can provide early signals of potential constraints or bottlenecks in the deployment of chemical and materials innovation.

Suggested factors to take into account include:

- **Trade and geopolitical risk:** concentration of supply chains and trade dependencies are recognised indicators of economic vulnerability. They can affect not only the raw materials supply, but also intermediate products and components used in the supply chain. Moreover, tariffs, export restrictions, and geopolitical tensions can affect access to key inputs or markets (Arriola et al., 2024).
- **Energy supply and price volatility:** Energy availability and price shocks can affect both upstream material production and manufacturing costs. Energy security is increasingly recognised as a core component of supply chain resilience (OECD 2025c).
- **Climate and environmental vulnerability:** Extreme weather events, water scarcity, and ecosystem degradation can disrupt production hubs and logistics networks. Environmental shocks are a growing source of supply chain disruptions (Anand 2024).
- **Market availability of strategic inputs:** beyond CRMs, other inputs (bio-based feedstocks, catalysts, specialty chemicals) may pose availability constraints due to limited production capacity or competing demand.
- **Knowledge and skills dependencies:** human capital shortages and scarcity of technological know-how can constrain innovation scaling. Vulnerability frameworks highlight economic and societal dimensions of emerging technologies (Farhadloo et al., 2025).
- **Conflict and systemic disruption risks:** armed conflicts, pandemics, or systemic shocks may cause abrupt supply disruptions, particularly in highly interconnected value chain (OECD 2025b).

Alongside the CRM assessment, these additional vulnerability factors can provide qualitative insights into potential constraints, systemic risks, or unintended trade-offs associated with innovative chemicals and materials.

6.2.1. Identification of chemicals and materials

Taking into account the system boundary developed for the environmental sustainability, the analysis should consider the following inputs and outputs entering the system, i.e.:

- Materials that compose the product or component under assessment, as described in the Bill of Materials (BoM). A Bill of Materials can be defined as a diagram that lists all the

components, intermediate assemblies, sub-components and parts necessary to produce one unit of a finished product, or end part (Cinelli et al., 2020).

- Chemicals that compose those materials, with CAS numbers.
- Chemicals used during supply chain processes (e.g. synthesis, formulation or surface treatment), whether they remain in the final material, for each step of the supply chain.
- Output flows of chemicals and materials that might be found in waste and by-products.

The sources of information for this phase can include the Bill of Materials, the Life Cycle Inventories used in the ESA, and other information from the supply chain.

6.2.2. Screening and flagging of Critical Raw Materials

Once the relevant materials and chemicals have been identified, the next step consists of screening the list of chemicals and materials against the EU list of Critical Raw Materials (EU, 2024e).

The identified substances are compared with the CRM list in order to determine whether any critical raw materials are present in the product system or its supply chain.

The results of this screening should be reported as a flagging exercise, highlighting the presence of CRMs in materials or processes and the stages of the supply chain where they occur.

This screening allows identifying potential dependencies on critical materials and supports further analysis of substitution options, recovery opportunities or alternative design solutions within the SSbD framework.

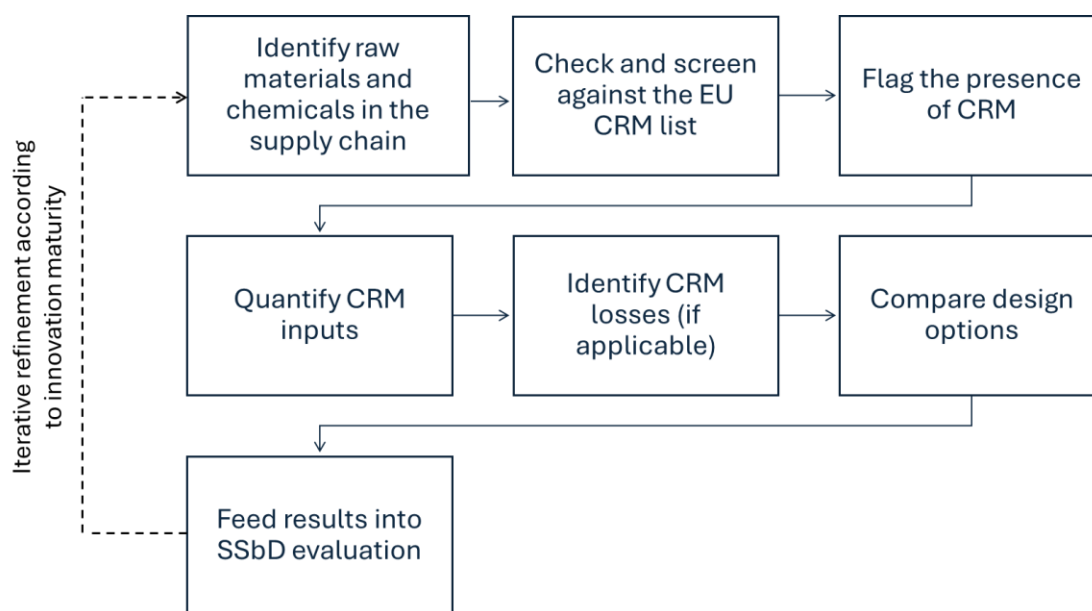
Based on the above phases, and depending on the level of innovation maturity and information availability, the SSbD practitioner could:

1. Compare CRM inputs across alternative design options, if applicable.
2. Identify stages where CRM losses occur.
3. Quantify, where possible, the mass of CRMs per functional unit.
4. Perform substitution and recovery checks: assess whether CRM losses could be reduced; check if alternative materials reduce CRM dependency, identify potential trade-offs with safety or environmental performance.

The results of the CRM assessment provide a basis for evaluating whether the intended innovation reduces dependency on CRMs, maintains it, or increases it. This information should complement safety, environmental and socio-economic performance.

The complete workflow for the assessment of CRMs is shown in Figure 31.

Figure 31. Operational workflow for CRM assessment within the SSbD framework.



Source: JRC

6.3. Economic assessment and evaluation of externalities

In the context of a life cycle sustainability assessment, economic considerations are assessed via the Life Cycle Costing (LCC) methodology. The LCC consists of accounting for all the costs that occur in the life cycle of a product with reference to one or more participants in the product system (Bianchi et al., 2021).

In the context of an SSbD study, LCC may be used to compare life cycle costs of alternatives only when applications have reached **high levels of innovation maturity** and costs can be estimated.

The cost analysis aims at detecting direct and indirect (hidden) cost drivers, or estimating improvements of planned product changes, including process changes within a life cycle or via product/process/component innovations. Moreover, an LCC assessment can support the identification of win-win situations and trade-offs in the life cycle of a product, once it is combined with LCA.

Monetisation of externalities

Externalities can be defined as “consequence of an activity that affects interested parties other than the organisation undertaking the activity, for which the organisation is neither compensated nor penalised through markets or regulatory mechanisms” (ISO, 2019). Monetising externalities allows converting measures of societal and biophysical impacts calculated in the environmental assessment into monetary units.

Assigning a monetary valuation for different environmental impact categories allows an aggregation into one single value (based on the currency chosen) from different environmental results. This requires applying a set of monetary valuation coefficient (MVC) to life cycle impact assessment methods. Note that such valuation methods are sometimes controversial, with a lack of acceptance among some stakeholders. Given the large variability of the MVC sets available in literature and in policy documents, the JRC performed a review (Amadei et al. 2021) and proposed a set of MVC to be applied in the context of the Ecodesign of energy-related products (Gama Caldas et al., 2024),

(Table 9). For some impact categories, however, it was not possible to give a recommendation on the related MVC.

Table 9. Set of monetary valuation coefficients as proposed in the context of the Eco-design Directive

Impact category		Unit of measure	Value
1	Climate change, total	€ ₂₀₁₉ /kg CO ₂ eq.	1.00x10 ⁻¹
2	Ozone depletion	€ ₂₀₁₉ /kg CFC-11 eq.	5.55x10 ⁺¹
3	Human toxicity, cancer	€ ₂₀₁₉ /CTUh	1.66x10 ⁺⁵
4	Human toxicity, non-cancer	€ ₂₀₁₉ /CTUh	9.19x10 ⁺⁵
5	Particulate matter	€ ₂₀₁₉ /disease incidence	7.28x10 ⁺⁵
6	Ionising radiation, human health	€ ₂₀₁₉ /kBq U ₂₃₅ eq.	-
7	Photochemical ozone formation, human health	€ ₂₀₁₉ /kg NMVOC eq.	1.20x10 ⁰
8	Acidification	€ ₂₀₁₉ /mol H ⁺ eq.	3.50x10 ⁻¹
9	Eutrophication, terrestrial	€ ₂₀₁₉ /mol N eq.	-
10	Eutrophication, freshwater	€ ₂₀₁₉ /kg P eq.	1.95x10 ⁰
11	Eutrophication, marine	€ ₂₀₁₉ /kg N eq.	3.27x10 ⁰
12	Ecotoxicity, freshwater	€ ₂₀₁₉ /CTUe	3.89x10 ⁻⁵
13	Land use	€ ₂₀₁₉ /pt	1.78x10 ⁻⁴
14	Water use	€ ₂₀₁₉ /m ³ water eq. of deprived wa-	5.08x10 ⁻³
15	Resource use, minerals, and metals	€ ₂₀₁₉ /kg Sb eq.	-
16	Resource use, fossils	€ ₂₀₁₉ /MJ	-

Source : Gama Caldas et al. 2024

The interpretation of these results should be performed in combination with internal costs analysis and can provide support for a comparative assessment of different alternatives.

6.4. Tiered approach for the Socio-Economic Assessment

As described in the previous sections, the socio-economic assessment should be applied in a tiered and iterative way (Table 10), starting with a simplified assessment in cases of low levels of maturity innovation and moving towards a full assessment when more data becomes available and the innovation reaches higher levels of maturity. The cost analyses, by comparison, may usually be applied only when the innovation is mature and costs may be more confidently ascertained.

The simplified assessment can be also applied by SMEs, which might have less resources and know-how with respect to performing a full socio-economic assessment.

Table 10. Tiered approach for the social and CRM assessment

	Simplified assessment	Full assessment
SOCIAL ASSESSMENT	- Flagging potential socio-economic issues in the value chain - Focus on a subset of fundamental indicators - Limitscope (system boundary covering only direct business partners) - Focus on materials sourcing and supply chain configurations based on different design options	- Extend the assessment to indicators beyond the fundamental ones - Stakeholder engagement - Alignment with the UNEP guidelines and/or ISO standard (e.g. use of functional unit)
CRM ASSESSMENT	- Screening against EU CRM list - Identification via BoM only - Qualitative flagging	- Quantification of CRM mass shares - Identification of country of origin - Substitution and recovery checks - Supply chain vulnerability assessment

Source: JRC

Example: socio-economic assessment in the (re)design of a membrane

To illustrate the application of the socio-economic sustainability assessment within SSbD, the (re)design of a membrane is analysed across three dimensions: molecular composition, production process and final product. As in the environmental assessment, the socio-economic analysis evolves along the innovation pathway, with increasing data availability and methodological depth.

- The socio-economic assessment, when applied at **molecular (re)design**, is currently not able to describe the performances of chemicals/materials (while, at level of intrinsic properties, potential negative impacts on health are already taken into account in the safety assessment). However, the forthcoming work of the Critical Chemicals Alliance (EC, 2025b.) on the mapping of critical molecules (such as those that are essential for strategic value chains and subject to dependency on a single third country or a few suppliers) could be a basis for future socio-economic assessments also at the level of molecular (re)design, helping identifying potential issues for competitiveness.
- In the context of the **process (re)design**, it can be evaluated if the changes in the production process and the application of environmental targets (e.g. 25% of water use impact reduction) can produce any change in the supply chain structure compared to a representative system. Alternative process configurations may be assessed for their implications on supply chain vulnerabilities and potential social risks, taking into account operations in the foreground system (e.g. for presence of safety measures and potential impacts on local communities) and secondary data for upstream stages. Quantification of CRM inputs per functional unit becomes possible. Potential CRM losses in process residues or catalysts can be identified.
- The **product (re)design** can be supported by a simplified socio-economic assessment in the initial and laboratory stages, in order to flag potential social risk in the supply chain and compare with a representative system. At industrial scale, a full socio-economic assessment can be performed, including the comparison of alternatives for the total societal costs, i.e. including both internal costs and monetised externalities. For the social assessment, primary data from manufacturing sites and key suppliers can be integrated with secondary data for

upstream and downstream stages (e.g. use and end-of-life). Reference scale scoring enables identification of hotspots across the full life cycle. CRM flows can be quantified across the membrane life cycle, including potential recovery at end-of-life. Design options can be evaluated for their effect on CRM dependency.

6.5. FAQs on the socio-economic assessment

Is the socio-economic sustainability assessment applicable at early development stages?

The ambition of the SSbD framework is to identify possible hotspots at early stages of the innovation process. Hence, the earlier the SSbD assessment is applied in the innovation, the higher is the possibility to reveal and address negative trade-offs on safety and sustainability aspects, including those that are related to socio-economic elements. Social LCA has been developed for the assessment of products and organisations and have been scarcely applied to in the case of emerging technologies. Hence, a simplified approach is proposed. More complete and quantitative socio-economic assessment can be applied as innovation matures and as more information on the production process is available.

How can I deal with qualitative data in the socio-economic assessment?

Qualitative data describes the attributes or properties of an object or an activity. For instance, the performance of an organisation concerning workers' health and safety can be assessed, describing the extent to which the company puts in place preventive measures (among other indicators). Descriptions of properties or performances can be categorised into classes and assigned numerical values, using reference scales and converting them in a scoring system in line with the other steps of the SSbD framework.

Should social indicators be aggregated into a single score?

Aggregation should be limited and applied cautiously. Compensation across different social topics or stakeholder groups should generally be avoided.

When is a quantitative CRM assessment relevant?

Quantification becomes more relevant at higher maturity levels, when comparing alternatives or assessing substitution and recovery strategies.

How should CRM results be interpreted?

CRM results should be interpreted as indicators of supply chain vulnerability and material dependency. They provide information on the presence, quantity and life cycle relevance of critical raw materials, helping to identify risks related to supply disruption, substitution challenges or recovery opportunities.

Is Life Cycle Costing relevant in all SSbD studies?

No. LCC is mainly relevant for mature innovations where cost data are available and for comparative assessments of alternatives.

7. SSbD Evaluation

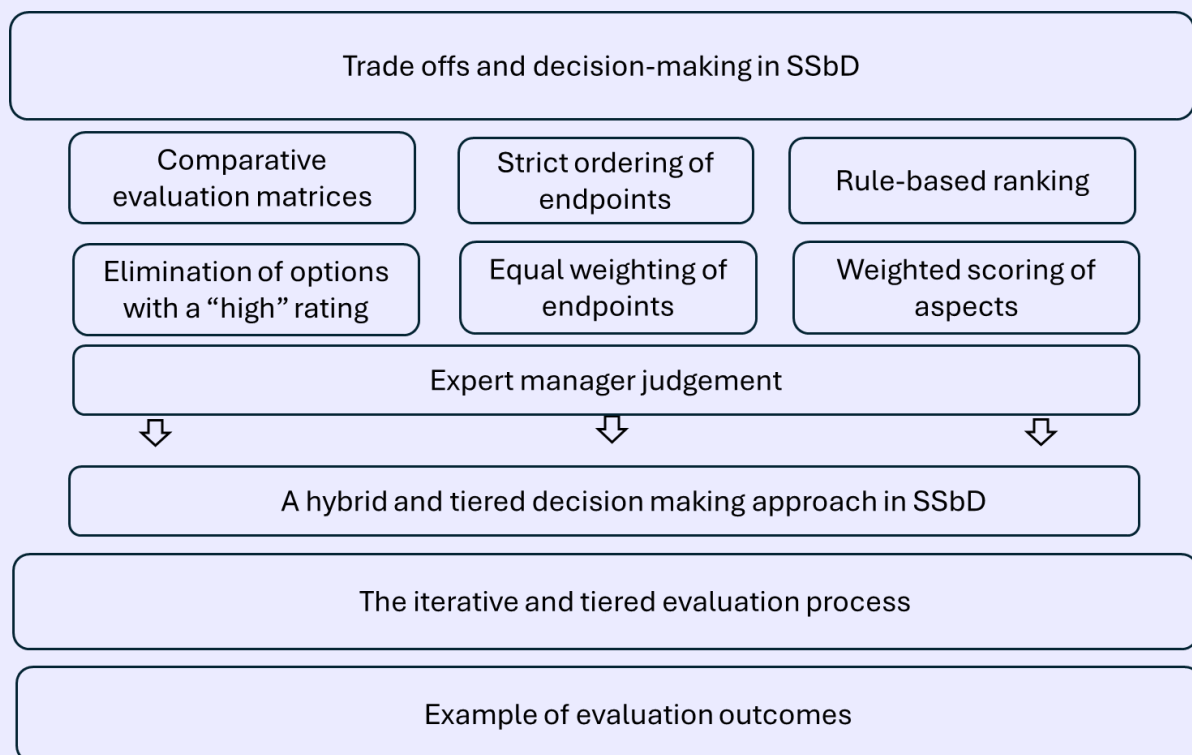
AIM OF THE SECTION:

The aim of the evaluation is to support the decision-making process along the innovation cycle within the frame defined in the scoping analysis. In the evaluation, the SSbD practitioner **compares the results** of the safety and sustainability assessment with the objectives, principles and decision-making rules and criteria defined in the scoping analysis in an iterative manner. The outcome of the evaluation will feed in the scoping analysis of the next SSbD iteration up to the point of fulfilling the SSbD principles including full safety and sustainability considerations.

This section describes:

- The strategies to identify trade-offs and guide decision making
- A tiered approach for decision making
- An example of dashboard for evaluation
- Example of evaluation outcomes

Figure 32. Structure of the SSbD Evaluation section



Source: JRC

7.1. Trade-offs and decision making in SSbD

Trade-offs between safety, environmental and socio-economic sustainability, functionality, and technical and economic feasibility aspects, are inherent to the application of the SSbD framework. Different strategies can be applied to support structured, transparent and proportionate decision-making when such trade-offs arise. With specific regard to safety and sustainability performances, decision making rules should always be established in order to limit as much as possible trade-offs (e.g. by considering the minimum requirements for each dimension), so that one aspect cannot overrule unacceptable weaknesses on the others (Dias et al., 2024).

The selection of an appropriate decision support strategy should be fit-for-purpose and consistent with the scope, purpose and decision context within the innovation, as defined during the scoping analysis (and problem formulation for safety and goal and scope for sustainability). In particular, the choice of the decision-support approach should be consistent with the stage of innovation, the availability and quality of information, the resources and time available, the intended decision objective such as screening, prioritisation, selection or optimisation, and the required level of transparency and traceability. In order to evaluate the results obtained in the safety and sustainability assessment, these should have an appropriate level of aggregation, as the analysis of a large number of indicators can be challenging when applying decision support strategies. While the possibilities for aggregation for, environmental and socio-economic results are described in the related chapters, it is important that the choices and weight schemes applied to obtain scores at dimension level (when possible) are transparently documented.

While aggregation may facilitate decision-making for environmental or socio-economic sustainability indicators, safety results should not necessarily be aggregated into a dimension-level score. Safety indicators represent fundamentally different types of hazards, consequences, likelihoods, exposure pathways, and vulnerable populations. Combining them through weighting schemes can mask critical risks and may create compensatory effects whereby favourable results for certain hazards or exposure scenarios offset unfavourable results for others. It may also lead to overly conservative or misleading conclusions, where adverse outcomes for certain hazards or exposure scenarios outweigh positive findings for others. Aggregation reduces the transparency of the safety assessment results. For this reason, safety assessments are reported as separate indicators, threshold exceedances, or risk categories rather than as aggregated indices.

In line with the tiered and iterative nature of the SSbD framework, the sophistication of the decision-support method should increase with the maturity of the innovation, the quality of the assessment results, and the potential consequences of the decision. Simpler and more precautionary approaches should be applied at early stages, while more formal and quantitative approaches may be justified at later stages provided that the underlying data and assumptions are sufficiently robust.

This section provides a comprehensive description of the commonly applied strategies (OECD, 2021) to navigate trade-offs and support the decision-making process. Table 11 summarises the most relevant elements

i. Comparative evaluation matrices (traffic-light or ranking schemes)

Comparative evaluation matrices should be used to support early-stage screening, prioritisation, and design orientation. It translates assessment results into categorical ratings, such as Green, Yellow, and Red, or equivalent ranking schemes, for each endpoint or indicator. These ratings are compared across the different options to identify relative performance, strengths and weaknesses, and

priority areas for redesign, rather than to demonstrate compliance with safety or sustainability criteria.

This approach should be applied primarily at the concept and early design stages, particularly when multiple alternatives are under consideration, quantitative data are limited, and clear and communicable outcomes are required. Qualitative or semi-quantitative information is generally sufficient, and resource and data needs are low to moderate.

The approach produces a visual comparative output that highlights areas of concern and supports discussion rather than automated decision-making. Uncertainty is typically high and is not formally quantified; it should therefore be addressed through conservative categorisation and clear documentation of assumptions. Transparency is high due to the simplicity and communicability of the results.

Strengths of this approach include clarity, ease of use and effective communication of key issues. Limitations include loss of quantitative detail and sensitivity to category definitions and boundary conditions, which should therefore be explicitly documented, as they may significantly influence the resulting comparisons.

ii. Elimination of options with a “high” rating (exclusion principle)

The exclusion principle should be applied when specific endpoints are identified as critical within the innovation objectives. Under this approach, any option that scores “high concern” for a predefined sensitive endpoint or indicator should be excluded from further consideration, irrespective of its performance with respect to other assessed aspects (Keeney & Raiffa, 1993).

Exclusion rules should be explicitly defined, scientifically justified, and limited to endpoints, indicators or other characteristics that are incompatible with innovation objectives. This approach should be applied primarily at early stages of innovation, particularly in precautionary contexts or where clear “no-go” criteria exist, to prevent lock-in to options that are fundamentally misaligned with innovation principles.

Screening-level assessment results are generally sufficient to support exclusion decisions, and resource and data needs are low. The approach is rule-based and produces a binary output, whereby options are either retained or eliminated, and it supports go/no-go and early filtering decisions. Uncertainty is managed conservatively by favouring protection.

Transparency is high, if exclusion criteria, thresholds and their relevance to the decision context are clearly documented. Strengths of this approach include strong protection and alignment with the precautionary principle. Limitations include the potential elimination of promising options that could be improved through redesign prematurely, highlighting the importance of well-justified and proportionate exclusion thresholds.

iii. Strict ordering of endpoints (hierarchical dominance)

Strict ordering of endpoints should be applied when clear, stable, and agreed priorities exist among safety, sustainability, or other innovation aspects. In this approach, endpoints are hierarchically ranked according to their relative importance, and the highest-ranked endpoint governs the overall preference ordering of options.

The hierarchy of endpoints should be explicitly defined and justified, for example based on regulatory requirements, policy objectives or organisational principles. This strategy should be used in

policy-driven, regulatory, or organisational contexts where such priorities are predefined and broadly accepted within the decision context, and it is most appropriate at early to mid-design stages.

Moderate and reliable assessment data should be available for the highest-ranked endpoints to support robust decision-making, while lower-ranked aspects may be assessed at a lower level of detail. The approach is deterministic and produces a clear preference ordering based on dominance, supporting selection decisions aligned with explicit values or mandates.

Uncertainty is managed implicitly through prioritisation rather than aggregation. Transparency is high provided that the hierarchy and its justification are clearly documented. Strengths of this approach include clarity, consistency, and alignment with policy objectives, while limitations include the reduced influence of lower-ranked aspects and the need for consensus on the endpoint hierarchy.

iv. Equal weighting of endpoints (simple additive scoring)

Equal weighting of endpoints may be applied as a baseline comparative approach when no explicit prioritisation among assessed aspects has been established. In this approach, all aspects are considered equally important, and categorical ratings are converted into numerical scores that are summed and aggregated to support comparison of options.

This strategy should be applied primarily at early to mid-stages of innovation, particularly when comparing similar options and when semi-quantitative assessment results are available. It is suited to decision contexts where the objective is relative ranking rather than optimisation.

The approach produces a single aggregated score per option and supports comparative selection decisions. Uncertainty remains moderate and is not explicitly quantified, while transparency is high due to the simplicity of the aggregation.

Strengths of this approach include ease of use, clarity, and its role as a neutral starting point in the absence of defined priorities. However, equal weighting should not be interpreted as value-neutral, as it implicitly assumes equivalent importance across all assessed aspects. The limitations of this assumption should be explicitly acknowledged, particularly where aggregation may obscure critical safety or sustainability concerns.

v. Rule-based ranking (logic-driven decisions)

Rule-based ranking should be applied when decision-making requires the use of explicit logical conditions or sequential rules that cannot be adequately represented through numerical aggregation. In this approach, preference ordering is determined through predefined logical statements that reflect innovation objectives and priorities identified during the scoping analysis (and problem formulation for safety and goal and scope for sustainability).

This strategy should be used primarily at mid to late stages of innovation, particularly for complex decisions involving conditional priorities, mixed qualitative and quantitative information, or organisational or regulatory logic. Moderate-quality assessment data are required to support the application of decision rules.

The approach produces a traceable ranking or decision outcome based on the consistent application of documented rules and supports complex prioritisation and selection decisions. Uncertainty is addressed through structured reasoning rather than formal quantification. Transparency is high if rules are clearly formulated, consistently applied, and transparently documented.

Strengths of this approach include flexibility, logical consistency, and the ability to capture complex preferences without arbitrary numerical scoring. Limitations include increasing complexity as the number of rules grows and the potential embedding of implicit weighting, which should be recognised and critically assessed.

vi. Weighted scoring of aspects (MCDA-type approaches)

Weighted scoring approaches, including multi-criteria decision analysis (MCDA), should be applied when design optimisation or other high-stakes decisions are required and when the potential consequences of the decision justify increased analytical complexity. In these approaches, assessed aspects are assigned explicit weights, and weighted scores are aggregated to support preference ordering among options. Recent literature highlights that MCDA can play a key role in SSbD by structuring complex decision problems, supporting the comparison of alternatives across safety, environmental, economic and social criteria, and improving the robustness and transparency of decision-making, particularly when multiple stakeholders and uncertainties must be considered (van Dulmen et al., 2026).

This strategy should be applied primarily at mid to late stages of innovation, when quantitative or semi-quantitative assessment results are available and stakeholder input can be used to inform and justify weighting choices. The suitability of this approach should be assessed considering available resources and the case-specific nature of weighting assumptions.

The approach produces a quantitative ranking or preference score and supports optimisation and final selection decisions. Uncertainty should be explicitly explored, for example through sensitivity or scenario analysis, and weighting assumptions should be transparently documented. Transparency is moderate to high, depending on the level of documentation and stakeholder involvement.

Strengths of this approach include systematic and reproducible handling of multiple priorities and the ability to evaluate the robustness of outcomes. Limitations include high resource requirements and sensitivity to subjective weighting choices, which should be carefully justified and communicated.

vii. Expert–manager judgement

Expert–manager judgement may be applied at any stage of innovation, particularly in data-poor, exploratory or strategic contexts. In this approach, decisions are made by expert panels or expert–manager groups and are informed by assessment results but are not determined solely through formal scoring or algorithmic procedures.

This strategy relies primarily on expert knowledge rather than predefined data requirements and supports exploratory, adaptive, and strategic decision-making. It produces qualitative or strategic decision outcomes, and resource and data needs are variable depending on the context.

Uncertainty is addressed through expert interpretation rather than formal analysis. Transparency depends on the extent to which expert judgement is structured, evidence-informed and documented, and whether professional or other guidance has been followed and referenced. To enhance traceability, the composition of expert groups, the basis for judgements and the rationale for decisions should be clearly documented.

Strengths of this approach include flexibility and the ability to integrate contextual and tacit knowledge. Limitations include lower reproducibility and the potential for bias, which should be recognised and mitigated where possible through structured procedures and documentation.

Table 11. Summary table with key elements for navigating trade-offs of the decision-making strategies

Decision strategy	Best suited for	Supported decision type	Data needs	Transparency	Innovation maturity	Strengths	Limitations
Comparative evaluation matrices (traffic-light / ranking schemes)	Screening and prioritisation when multiple options are considered Rapid comparison under uncertainty	Screening, prioritisation, design direction	Low	High	Concept → early	Simple, communicable, highlights areas of concern, supports discussion	Loss of quantitative detail; results sensitive to category definitions
Eliminate “high” rating (exclusion principle)	Screening when non-negotiable criteria apply Prevents lock-in of clearly problematic options	Go/no-go, filtering	Low	High	Concept → early	Prevents unsafe lock-in; aligns with precautionary principle	May eliminate options with redesign potential; requires robust justification
Strict ordering of endpoints (hierarchical dominance)	Policy- or organisation-driven decisions with clear priorities Reflects explicit priorities	Selection aligned with explicit priorities	Moderate	High	Early → mid	Clear, defensible, policy-aligned	Lower-ranked aspects may be undervalued
Equal weighting of endpoints (simple additive scoring)	Comparison when no explicit prioritisation exists Neutral baseline for comparing similar options	Comparative selection	Moderate	High	Early → mid	Simple, transparent, neutral starting point	Assumes equal importance; may mask critical risks
Rule-based ranking (logic-driven decisions)	Complex, conditional decisions Captures logical priorities without full quantification	Complex prioritisation, selection	Moderate	High	Mid → late	Captures complex preferences; avoids arbitrary scoring	Can become complex; may embed implicit weighting
Weighted scoring of aspects (MCDA-type approaches)	Optimisation Appropriate when data quality and stakes are high	Optimisation, final selection	High	Moderate-high	Mid → late	Systematic, reproducible, manages priorities explicitly	Resource-intensive; weighting may be contentious
Expert-manager judgement	Exploratory or strategic decisions Complements formal methods under uncertainty	Exploratory, adaptive, strategic decisions	Variable	Moderate	Any	Flexible, integrates contextual knowledge	Lower reproducibility; potential bias

Source: JRC

7.2. A hybrid and tiered decision-making approach

An optimal strategy that can be applied across all innovation stages in the SSbD context is not a single method, but a layered, adaptive decision strategy that evolves with the maturity of the innovation while remaining conceptually consistent.

Currently no single method can capture the full complexity of chemical and material safety, sustainability, and functionality across the life cycle. Within the SSbD framework, a hybrid decision-making approach is recommended when trade-offs cannot be credibly resolved using a single decision-support strategy, or when assessment results differ in maturity, robustness or relevance across safety and sustainability aspects.

A hybrid, tiered approach identifies unviable options early, increases analytical rigour as information improves, maintains transparency and proportionality, and supports iteration and redesign rather than one-off decisions.

The strategy should be life-cycle-based, tiered, transparent, precautionary where uncertainty is high, and adaptive to new information. Decisions should always be traceable to objectives defined in the scoping analysis.

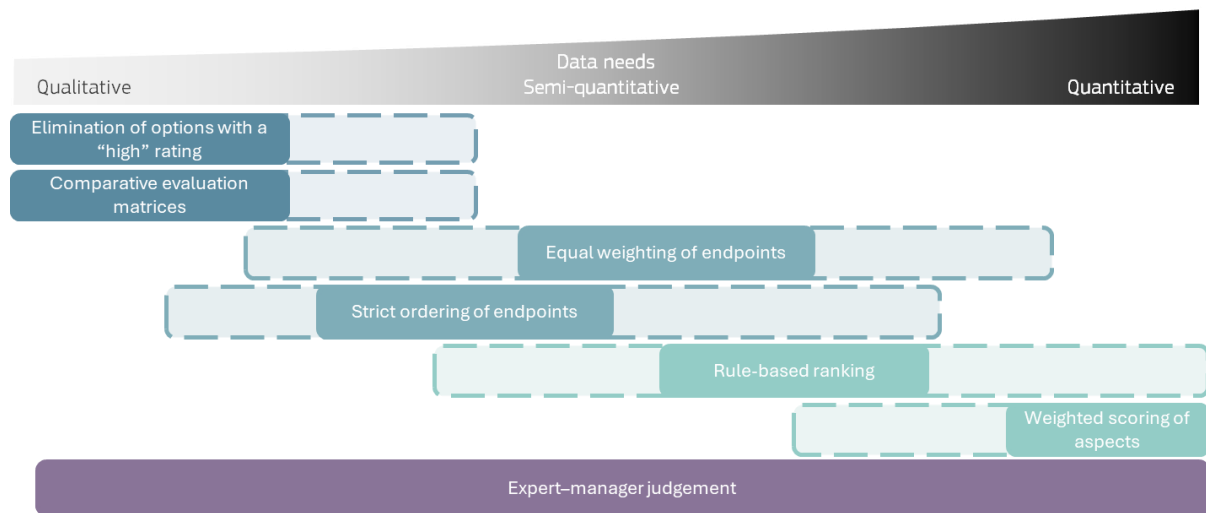
The hybrid approach combines complementary strategies such as rule based decisions, structured comparison, quantitative optimisation or weighted scoring, applied progressively and iteratively across the innovation in a structured and transparent manner to enable informed comparison and optimisation

In this approach expert-manager judgement acts as an integrating and validating layer supporting interpretation of results, resolution of borderline cases, and assessment of feasibility, redesign potential, and uncertainty. The role of expert judgement, the expertise involved, and the rationale for any judgement-based decisions should be clearly documented to maintain transparency and traceability.

Figure 33 provides an example of a hybrid and tiered decision-making approach

- **Early stages:** Non-negotiable safety or sustainability criteria can be applied first to eliminate clearly unwanted options. With comparative evaluation matrices remaining alternatives are then compared using traffic-light or ranking matrices to identify major concerns and redesign priorities. Expert judgement should guide interpretation due to high uncertainty and limited data.
- **Mid stages:** The strategy evolves to include rule-based ranking and equal or lightly weighted scoring. Conditional logic should be used to reflect priorities and life-cycle considerations. Semi-quantitative data should support more structured comparison, while expert judgement remains essential to interpret trade-offs and guide iteration.
- **Late stages:** The strategy incorporates MCDA-type weighted scoring, supported by high-quality quantitative data. Rule-based constraints should still be applied when decision-making requires the use of explicit logical conditions or sequential rules that cannot be represented numerically. Sensitivity and uncertainty analyses should be conducted, and expert judgement should be used to validate outcomes and address residual trade-offs.

Figure 33. Example of a hybrid decision-making approach

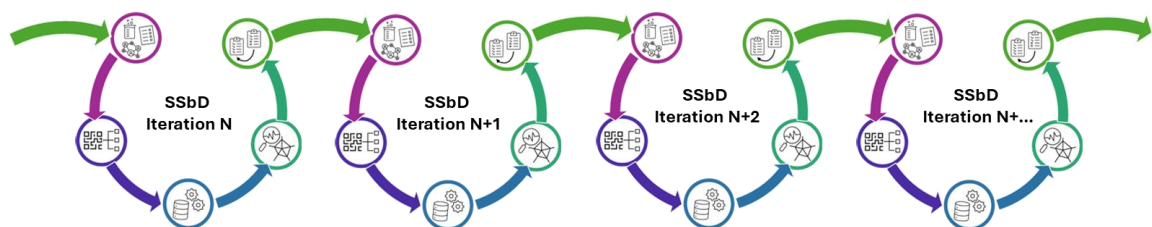


Source: JRC

7.3. The iterative and tiered evaluation process

The application of the SSbD framework follows the maturity of the innovation according to an iterative approach that allows a tiered assessment (see Figure 10). Figure 34 illustrates the iterative process of the SSbD and how for a given iteration (N), the outcome of the evaluation will feed into the scoping analysis of the subsequent iteration (iteration N+1). The outcome of the evaluation (see Section 7.4.) will depend on the results of the SSbD assessment, the scoping analysis and defined decision rules (see Section 3.3) and the decision-making strategy (see Section 7.2) applied.

Figure 34. Iterative process of the SSbD



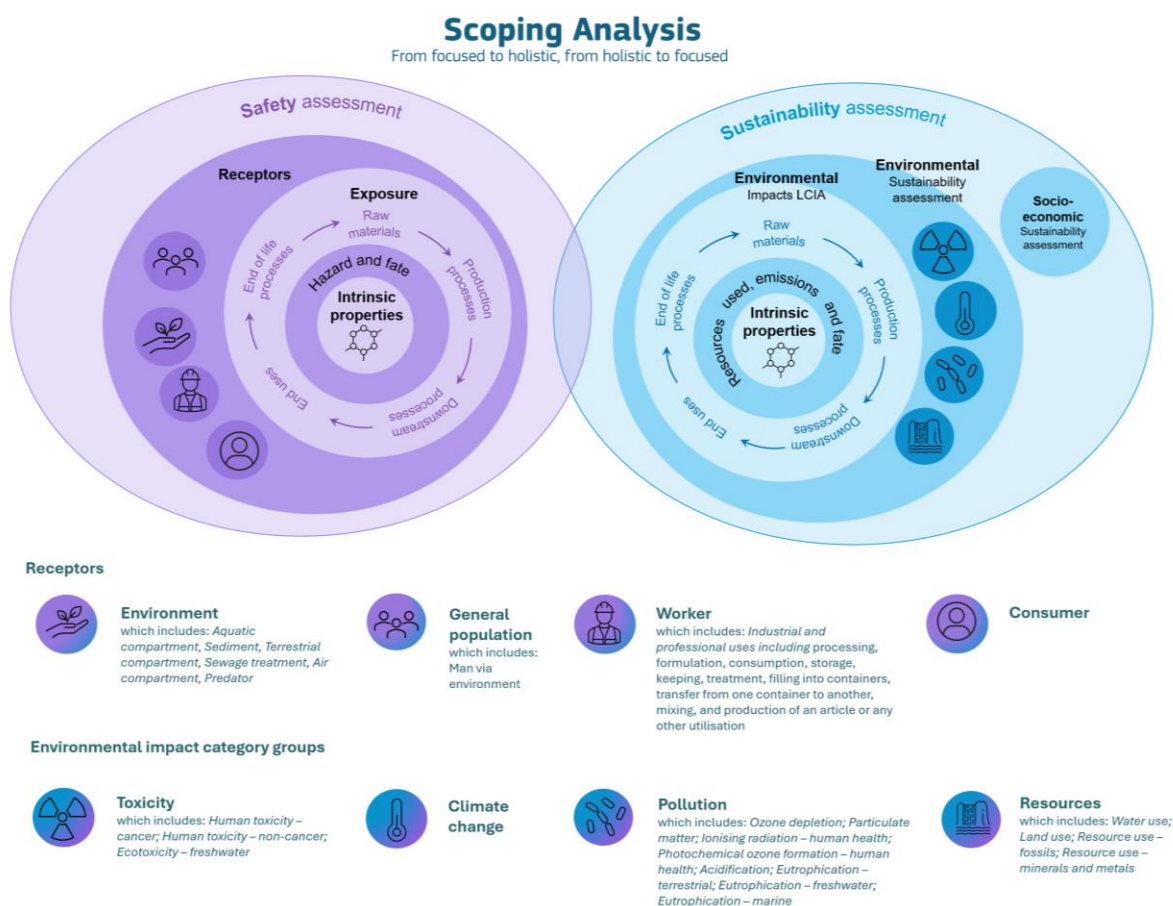
Source: JRC

The outcomes of the evaluation reflect the iterative nature of the SSbD framework where early concepts are assessed and progressively improved and refined by collecting and generating new information and data. The tier assessment defines the level of depth and complexity in the assessment process and represent the progression in analytical detail, and the related data requirements, quality needs and degree of decision confidence. Via new SSbD iterations, the scoping analysis is revisited, and the innovation is reassessed.

Figure 36 below exemplifies the evaluation and decision-making process along the innovation, when the SSbD framework is applied. This generic example is about innovation being applied at the product level, with the goal of improving the design for end of life, by selecting a biodegradable material.

On the left side, the elements of the SSbD framework are reported, including the scoping analysis and the safety and sustainability assessment results dashboards. Safety and sustainability assessment is a key element of the SSbD framework and includes the holistic assessment of safety and sustainability (both environmental and socio-economic) aspects along the entire life cycle of the chemical/material. Figure 35 gives a graphical overview of the different assessments that are undertaken and their main aspects.

Figure 35. Graphical representation of the main elements of the safety and sustainability assessments in SSbD.



Source: JRC

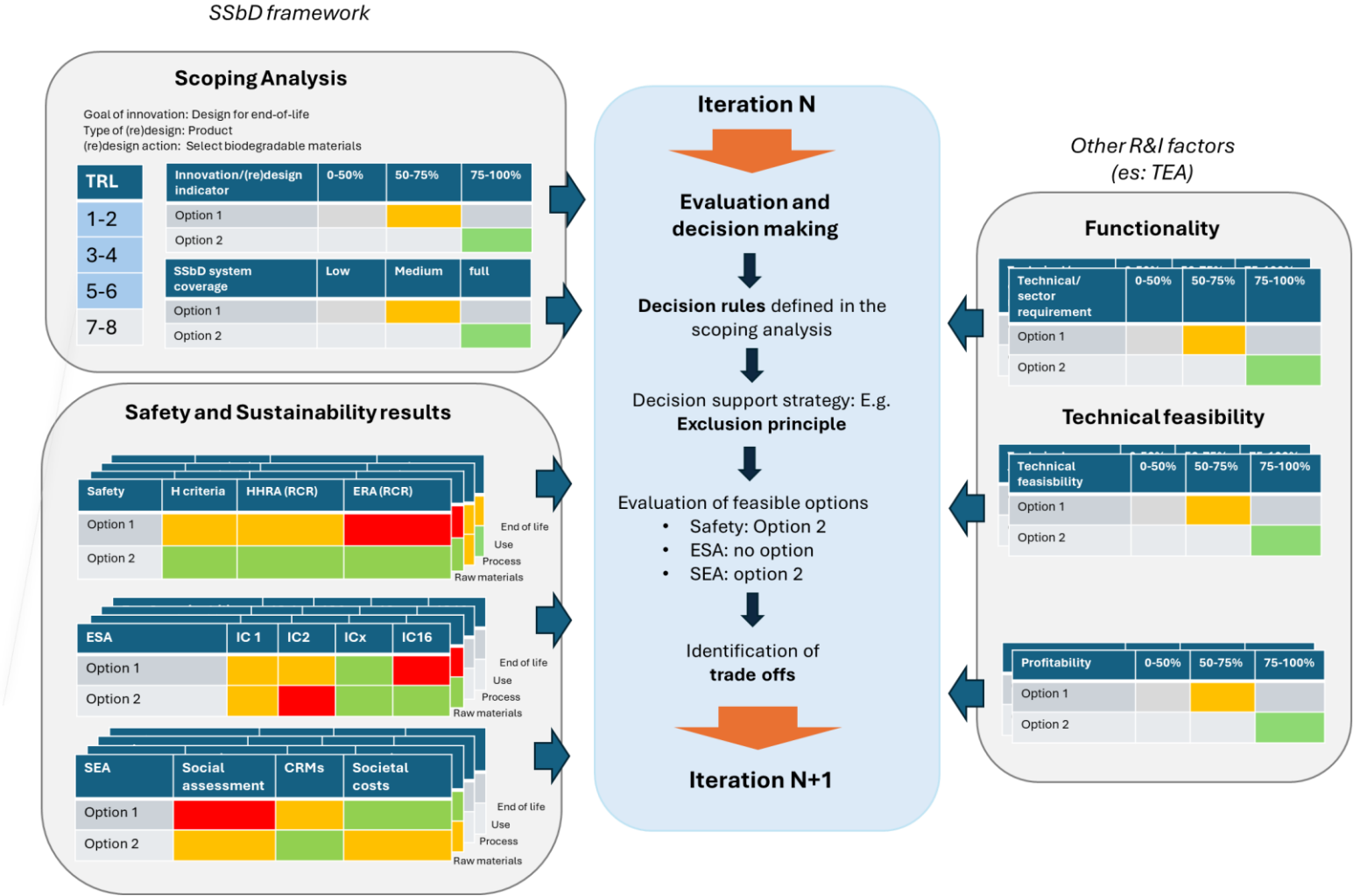
The uncertainty of the assessment should also be considered in the dashboard. On the left side, other aspects which are commonly considered and evaluated in the R&I, such as the functionality, the technical feasibility or the profitability, are reported as well.

The central part is about the evaluation and decision making, the outcome of which can be either feeding into the next iteration along the innovation, by reviewing the most critical aspects, or adding other aspects for the actual fulfilment of the SSbD principles. The decision-making rules defined in the scoping analysis are applied here to inform the overall evaluation, taking into account aspects related to the innovation and the fulfilment of the SSbD principles.

It should be noted that the application of the SSbD Framework is meant to support the decision-making process at any stage of innovation. According to the maturity of the innovation, the most

suitable strategy and approach may be chosen to evaluate the different aspects considered, and to support the decision-making process, as explained in the sections above.

Figure 36. Graphical exemplification of evaluation and decision making in the context of innovation, when applying the SSbD framework



7.4. Examples of evaluation outcomes

The evaluation stage presents the results of the safety and sustainability assessment and compares them in an iterative manner with the objectives, principles and decision rules defined in the scoping analysis, as described in section 7.3. Outcomes of the evaluation process can be that:

- (i) Additional information is needed/ uncertainty should be reduced, with regard to the safety and sustainability assessment results; and/ or
- (ii) Scope should be extended; and/ or
- (iii) objectives should be refined; and/ or
- (iv) (re)design should be revised; and/ or
- (v) after several re-iterations of the SSbD, it is expected that all possible refinements will have been applied and a sufficient degree of certainty has been achieved, regarding the safety and sustainability assessment.

The outcome of the evaluation will depend on the maturity of innovation (e.g. TRL), the associated uncertainty and also the objectives, principles and decision-making rules that were defined during the scoping analysis for each SSbD iteration. The outcome of the evaluation informs the scoping analysis of the subsequent iteration by identifying information gaps to reduce uncertainty with regards to the assessment and completeness of the SSbD.

Below, illustrative examples are presented, showing the different possible outcomes described above in (i-v). These examples are illustrative only and do not correspond to any specific iteration or assessment tier (See The SSbD framework in a nutshell), since any of these outcomes might occur during any iteration of the SSbD implementation and across all assessment tiers and innovation stages.

Example:

- **The innovator** is a packaging producer developing a new flexible food contact packaging film to replace conventional fossil-based plastic packaging for fresh food applications. The formulation is based on a bio-based polymer matrix, for example polylactic acid (PLA) blended with biodegradable co-polymers and functional additives to achieve suitable flexibility, sealing properties and shelf-life performance
- **The intended innovation** is a packaging material (**product (re)design**) aiming to reduce dependence on fossil-based plastic, using renewable raw materials and with improvements to the end-of-life options (e.g., recyclability or compostability). The packaging is used for fresh food products, such as fruit, vegetables, bakery products, or dry food items.

I. **Additional information is needed/ uncertainty should be reduced**

Evaluation outcome: Early SSbD screening confirms that the packaging film is bio-based and biodegradable, but there is uncertainty about chemical additives used to improve flexibility. The migration of additives into food is not well understood and there are insufficient long-term toxicity data to support a robust assessment.

Next iteration action(s):

- Conduct migration testing under different temperatures and storage conditions

- Generate toxicological data for additives
- Improve exposure assessment
- Document SSbD implementation, including iterations, scoping analysis, assessment results, trade-offs, and decision-making rules

II. Scope should be refined

Evaluation outcome: The system boundaries are too narrow to quantify key environmental impacts. The evaluation initially focuses only on the packaging material itself, but early life cycle thinking reveals that upstream raw material sourcing and end-of-life scenarios may significantly influence sustainability.

Next iteration action(s):

- Include a broader life cycle and value chain perspective in the SSbD assessment
- Expand the scope to quantify the impacts of:
 - Agricultural production of bio-based feedstock (e.g. land use, eutrophication, eco-toxicity)
 - Other supply chain aspects (e.g., energy use, transport)
 - End-of-life scenarios (e.g. recycling, composting, landfill leakage)
- Document SSbD implementation, including iterations, scoping analysis, assessment results, trade-offs, and decision logic.

III. Objectives should be refined

Evaluation outcome: Testing shows the film is only biodegradable under industrial composting conditions, which are not widely available. The original objective of “fully biodegradable packaging” is too broad or unrealistic in real-world conditions.

Next iteration action(s):

- Refine objective to:
 - “Packaging compatible with existing recycling streams” or
 - “Home-compostable under ambient conditions”
- Align sustainability goals with actual waste infrastructure
- Document SSbD implementation, including iterations, scoping analysis, assessment results, trade-offs, and decision logic

IV. (Re)design should be refined

Evaluation outcome: To achieve home compostability, the current formulation performs poorly. It has low strength and a short shelf life. A trade-off is identified between performance/ poorer functionality and environmental sustainability aspects.

Next iteration action(s):

- Reformulate material (e.g. adjust polymer blend or plasticisers)

- Reduce or replace problematic additives
- Improve barrier properties while maintaining safety
- Reiterate the assessment, focusing on ESA to check whether trade-off with key performance aspect still exist
- Document SSbD implementation, including iterations, scoping analysis, assessment results, trade-offs, and decision logic

V. **All refinements are applied**

Evaluation outcome: After multiple iterations, sufficient confidence in safety and sustainability is achieved for the decision that needs to be supported, based on the scoping analysis.

- Additives are evaluated as safe (low migration, low toxicity)
- Material meets revised objective (e.g. recyclable or home-compostable)
- Performance is acceptable for market use
- Life cycle assessment confirms environmental benefits

Next action(s):

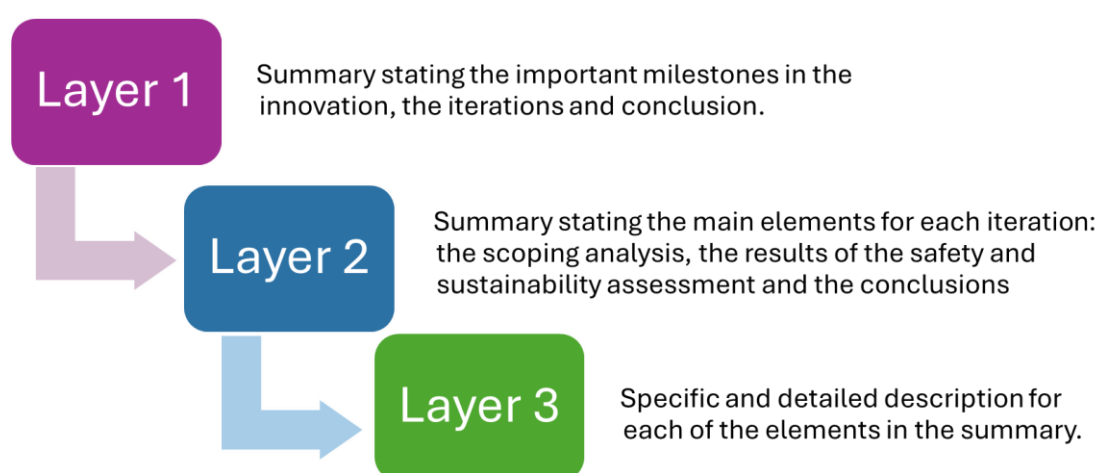
- Proceed to commercialisation, including fulfilling compliance requirements
- Document SSbD implementation, including iterations, scoping analysis, assessment results, trade-offs, and decision logic

8. Documentation

After each iteration, the SSbD practitioner should document the results of the evaluation, including the scoping analysis, the results of the safety and sustainability assessment as well as the fulfilment of the SSbD framework principles. This is critical to ensure the adherence to the SSbD framework in a transparent manner, outlining the actions and objectives for the subsequent iteration and ensuring traceability of the tiered safety and sustainability assessment.

According to Tables 21, 22 and 23 proposed in the 2025 SSbD framework (Garmendia Aguirre et al., 2025a), the documentation can be layered based on the complexity and depth needed for each of the milestones and aspects covered but should always demonstrate that the SSbD concept has been followed and that the SSbD principles have been achieved (Figure 37).

Figure 37. Layered representation of the information



Source: JRC

Example: Life cycle actors' engagement

Table 12. Layer 1. Summary of the involvement of life cycle actors in the SSbD iterations. (Extraction from Table 21 of the revised 2025 SSbD Framework):

	Life cycle actors	Iteration 1	Iteration 2	Last iteration
Life cycle Actors' involvement	Raw material supplier			
	Chemical manufacturer			x
	Formulator	x	X	x
	Product producer		X	x
	Waste manager			
	Other			

Source : Garmendia Aguirre et al., 2025a.

Table 13. Layer 2. Summary of actors in the life cycle and summary of type and depth of engagement. Extraction from table 22 of the revised SSbD Framework:

			Iteration 1	Iteration 2	Last iteration3
Actors in the Life cycle	Actors' involvement	Raw material supplier			
		Chemical manufacturer			x
		Formulator	x	x	x
		Product producer		x	x
		Waste manager			
		Other			
	Degree of involvement	Informative			
		Collaborative		x	x
		Other			
	Type of involvement	NDA			
		Partnership			
		Other		x	x
	Sharing mechanisms	Letter of access			
		Patent license			
		Block chain			
		Other		x	x
	Roles and responsibilities in the SSbD	Safety		x	x
		Sustainability			x
		Chemical//material			x
		Process(es)			
		Products		x	x
		Other			

Source : Garmendia Aguirre et al., 2025a.

Table 14. Layer 3. Detailed mapping of actors in the life cycle and description of the engagement mechanism. Table 23 of the revised SSbD Framework

Stakeholder information sheet		
Stakeholder	Name:	xxx
	Type of stakeholder	worker, supplier, customer.....
	Interest:	chemical, process, product, acceptance
	Influence:	acceptance, Resistance, Neutral
	Relevance:	Very High, high, medium, low, very low
Purpose of engagement	SSbD awareness, collaboration	
Strategy and approach for engagement	How it has been approached • Survey • Meeting • Workshop • Email • Questionnaire	
Type of engagement	Type	B2B, B2C, Consortia
	Mechanism	NDA, Consortia
	Roles and responsibilities	Provide detail on the roles and responsibilities
	Contributions	Provide details on the contributions: Scoping, decision rules, alternatives, data, evaluation....
Engagement/communication	Frequency	Daily, Monthly, ...
	Channel	Meeting, email....
	Type of information	

Source : Garmendia Aguirre et al., 2025a.

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List of abbreviations and definitions

Abbreviation	Definition
AOP	Adverse Outcome Pathways
BAT	Best Available Technologies
BAT-AEL	BAT Associated Emission Level
BAT-AEPL	BAT Associated Environmental Performance Level
BREF	BAT Reference Document
CLP	Classification, Labelling and Packaging
CRM	Critical Raw Materials
CSR	Chemical Safety Report
CSS	Chemicals Strategy for Sustainability
DEA	Data Envelopment Analysis
DG ENV	Directorate General – Environment
DG RTD	Directorate General – Research and Innovation
DNEL	Derived No Effect Level
EC	European Commission
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemicals Agency
ENES	Exchange Network on Exposure Scenarios
EPA	Environmental Protection Agency
ERC	Environmental Release Category
ES	Exposure scenario
EU	European Union
FAQ	Frequently asked question
FU	Functional Unit
GHE	Green House Emissions
HAZID	Hazard Identification
HAZOP	Hazard and Operability Study
ISES	International Society of Exposure Science
ISO	International Organization for Standardization

IUPAC	International Union of Pure and Applied Chemistry
JRC	Joint Research Centre
LCA	Life Cycle Assessment
LCI	Life Cycle Inventory
LCIA	Life Cycle Impact Assessment
LOPA	Layer of Protection Analysis
MCDM	Multi-Criteria Decision Making
MODM	Multi-Objective Decision Making
NAMs	New Approach Methodologies
NDA	Non-Disclosure Agreement
OECD	Organisation for Economic Co-operation and Development
PC	Product category
PEF	Product Environmental Footprint
PNEC	Predicted No Effect Concentration
PROC	Process category
PUC	Product Use Categories
QSAR	Quantitative Structure–Activity Relationship
R&I	Research and Innovation
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SDG	Sustainable Development Goal
SDS	Safety Data Sheet
SMILES	Simplified Molecular Input Line Entry System
SSbD	Safe and Sustainable by Design
SU	Sector of use
SVHC	Substance of Very High Concern
TF	Descriptor list for technical functions
TOPSIS	Technique for Order Preference by Similarity to Ideal Solutions
TRA	Targeted Risk Assessment
TRL	Technology Readiness Level
UVCB	Unknown or Variable Composition, Complex Reaction Products, or Biological Materials

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Annexes

Annex A. Scoping analysis: guiding questions to define the intended innovation and SSbD Scenarios

The present Annex complements the information provided in Section 3 to define the innovation. The checklist and questions shown in Table A.1, Tables A.2 and A.3 are neither exhaustive nor compulsory, but they are useful as a starting point for the Scoping Analysis and definition of the SSbD Scenario, and the identification of hot spots and tailoring the safety and environmental sustainability assessments.

Table A.1. Example of guiding checklist for building the SSbD Scenario

Scenario building sheet			Reply	Uncertainty (Low-mid-high)
SSbD System definition	Chemical(s)/material(s)	Raw material(s)		
		Chemical(s)		
		Material(s)		
		Auxiliaries		
	Process(es)	Raw material extraction		
		Synthesis		
		Processing		
		End of Life		
	Product(s)	Type of Product(s)		
		Sector(s)		
		User(s)		
Actors in the Life cycle	Actor' involved	Raw material supplier		
		Chemical manufacturer		
		Formulator		
		Product producer		
		Waste manager		
		Other		
	Actors' involvement	B2B		
		B2C		
		Consortia		
		Other		
	Degree of involvement	Informative		
		Collaborative		
		Other		
	Type of involvement	NDA		
		Partnership		
		Other		
	Sharing mechanisms	Letter of access		
		Patent license		
		Block chain		
		Other		
	Roles and responsibilities in the SSbD	Safety		
		Sustainability		
		Chemical//material		
		Process(es)		
		Products		
		Other		

Scenario building sheet					Reply	Uncertainty (Low-mid-high)		
Intended innovation	Reason of implementation	Innovation	Incremental					
			Breakthrough					
		Other						
	Objective of the implementation	Safety and sustainability assessment						
		Improvement of	Safety of	Chemical				
				Material				
				Process				
				Product				
			Sustainability of	Chemical				
				Material				
		Process						
			Product					
		Functionality						
		Other						
	Type of (re)design	Molecular						
		Process						
		Product						
		Other						
	Indicator	Safety related						
		Sustainability related						
		Functionality related						
		Other						
	Criteria/ decision rules	Safety related						
		Sustainability related						
		Functionality related						
		Combined						
	Maturity of	The innovation/ (re)design	Low					
			Medium					
High								
The SSbD implementation		Simplified						
		Intermediate						
		Full						

Source: JRC

Table A.2. Example of possible guiding questions to describe the chemical/material under assessment, the processes and product applications of the SSbD system under study

Chemical/ material definition	1. Are the chemical(s)/material(s) known? 2. If yes, provide the chemical/material identity information, for example: ☐ Name of the chemical/material (IUPAC name, trade name...) ☐ Composition ☐ Numerical identifiers (EC, CAS, INDEX, UFI, ERM....) ☐ Information related to molecular and structural formula ☐ Other
Processes related to the chemical/ material under study	3. Are the production processes known? 4. If yes, select which of the following(s) better represent the process under study ☐ The chemical/material is consumed or used for chemical processing to be transformed into another chemical/material. ☐ The chemical/material is intentionally added as a component in a mixture/formulation process. ☐ The chemical/material is used in the manufacturing of a product and is not meant to be part of the final product. ☐ The chemical/material is used in the manufacturing of a product and is meant to be part of it. ☐ End of Life management (waste disposal or recovery) of the chemical/material. ☐ Other
Product application(s) related to the chemical/ material under study	5. Is the final product/application known? 6. If yes, define the final product/application(s) to the detail that is possible by for instance collecting the following information: ☐ The description of the product ☐ Industry sector of the product (if applicable) ☐ Function of the chemical/material in the product ☐ Product specific, safety, sustainability, and functional needs ☐ Other 7. Based on the application, does/will the chemical/material under study follow specific requirements based on existing legislation? (e.g. food contact material, plastic packaging, cosmetics, Best Available Techniques, etc.)
Life cycle of the chemical/ material under study	8. Draft of the life cycle of the chemical/material to assess (this includes the raw materials with suppliers, the downstream customers – if any, uses, and end-of-life) 9. Based on the draft of the life cycle, define the system boundaries of your chemical/material study for the assessment

Source: JRC

Table A.3. Guiding questions to define the innovation under study. Some questions are in common for each level of the (re)design and others are more specifically for each of the three levels (molecular, process, product).

Definition innovation objectives	1. What is the goal of your innovation? 2. What is the type of innovation? 3. Is there any variation compared to the initial system? 4. What are the alternatives you are considering for your innovation goal?
(Re)design	5. What are the (re)design actions accompanying the fulfilment of the goal? (for instance, substitution of a SVHC, reduction of the water consumption during the chemical/material production process, etc) 6. Select the type of (re)design that better representing the (re)design action: ☐ Development of a chemical/material: Molecular (re)design ☐ Development/Improvement of an application: Product (re)design ☐ Development/Improvement of a process: Process (re)design
Indicators	7. For each (re)design action provide the list of the indicators and criteria to assess the implementation of the goals. 8. Define the decision-making purpose, rules and strategies
Preliminary study for the expected hotspots	9. Could you at this stage according to existing studies on the selected alternatives be able to preliminary identify potential hot spots? (e.g. water consumption, workers exposure) 10. Could you at this stage identify the expected life cycle stage more affected by the innovation (either positively or negatively)?
Molecular (re)design	11. Is there any existing chemical/material that can be used as a reference to compare the results of the SSbD study? 12. If yes, which of these options represent better the reference? ☐ Chemical/material with similar structure ☐ Chemical/material fulfilling the same function ☐ Representative Chemical/material as for the definition of the PEF method ☐ Other criteria to define the benchmark 13. At which innovation maturity level (e.g. Technology Readiness Level (TRL)) is the chemical/material under development?
Process (re)design	14. Does the improvement of the process require a new technology? 15. If yes, at which innovation maturity level (e.g. Technology Readiness Level (TRL)) is the new technology(ies) for the process improvement? Or is the technology already on the market? 16. Provide information about the new technology needed for the improvement of the process, for instance: the characteristics, the energy and auxiliaries consumed, its emissions and waste generated, etc...
Product (re)design	17. Does the (re)design of the product/application involve a new application? 18. If yes, at which innovation maturity level (e.g. Technology Readiness Level (TRL)) is the new technology(ies) for the product improvement? Or is the technology already on the market? 19. Provide information about the new technology needed for the improvement of the product/application

"Alternative technologies" refer to the general innovation under study. Alternative technologies for instance can refer either to alternative raw materials, production processes or alternative chemical/material, etc.]

Source: JRC

Annex B. Data sources, methods, tools and checklist for safety assessment

B.1. Hazard prediction tools

For (eco)toxicological information prediction, there is a plethora of quantitative structure–activity relationship models (QSARs) and tools integrating these models and a comprehensive overview is out of the scope of this report. In this guidance, the following examples of available QSAR resources are listed:

- The OECD [QSAR Toolbox](#) (OECD, 2026) is a type of software for retrieving chemical and toxicological data, finding analogues, and building categories based on chemical and mechanistic similarity, and for predicting substance properties based on data from similar chemicals.
- The JRC [QSAR Model Database](#) (EC, 2026f) is an archive providing information on the validity of QSAR models that were submitted to JRC's EU Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM). It provides information on 154 QSAR models for various endpoints.
- The Danish EPA [\(Q\)SAR Database](#) (Danish EPA, 2026) is a collection of structural information and QSAR predictions, containing structural information for approximately 170 000 chemicals. It contains QSAR predictions for more than 40 endpoints.
- The US EPA [EPI Suite](#) (US EPA, 2026b) is a type of software that predicts various physical-chemical properties and environmental fate endpoints and also include models for environmental transport

This information can be completed with *in vitro* assays and *in vivo* studies in higher tiers, as more data is needed for the completeness of the assessment, and higher certainty is needed for a conclusive classification and assessment.

Plenty of new approach methodologies (NAMs) for risk assessment have been developed in the last decades, but only some are included in OECD Test Guidelines (TGs) for regulatory implementation. Establishing an OECD TG is a formal process aimed at international use, according to the Mutual Acceptance of Data (MAD). However, these methods may be used in the context of SSbD, provided that they have a well-defined 'context-of-use' and are demonstrated to be scientifically valid. Several mechanisms have been proposed to assess the readiness of NAMs, with the aim of accelerating their use in risk assessment (Haase et al., 2024).

QSAR models are also being developed to predict midpoints from chemical structures and to identify sustainability red flags, such as global warming potential or ozone depletion potential (Sgariboldi et al., 2026).

For mixture classification purposes there are numerous of commercial and free tools such as Mixclass, an online mixture classification tool according to CLP (Mixclass, 2026). These tools calculate hazard classes and categories for mixtures based on the classification and concentration of its ingredients.

For hazard characterisation and derivation of DNEL, SECO-DNEL Tool (Simple European Calculator Of DNEL) provides a transparent platform that implements a consistent and well-accepted methodology for deriving DNELs. The SECO-DNEL Tool is an Excel-based tool developed by the Swiss authority SECO to calculate DNELs for various exposure scenarios (SECO, 2026).

B.2. Use description methodologies

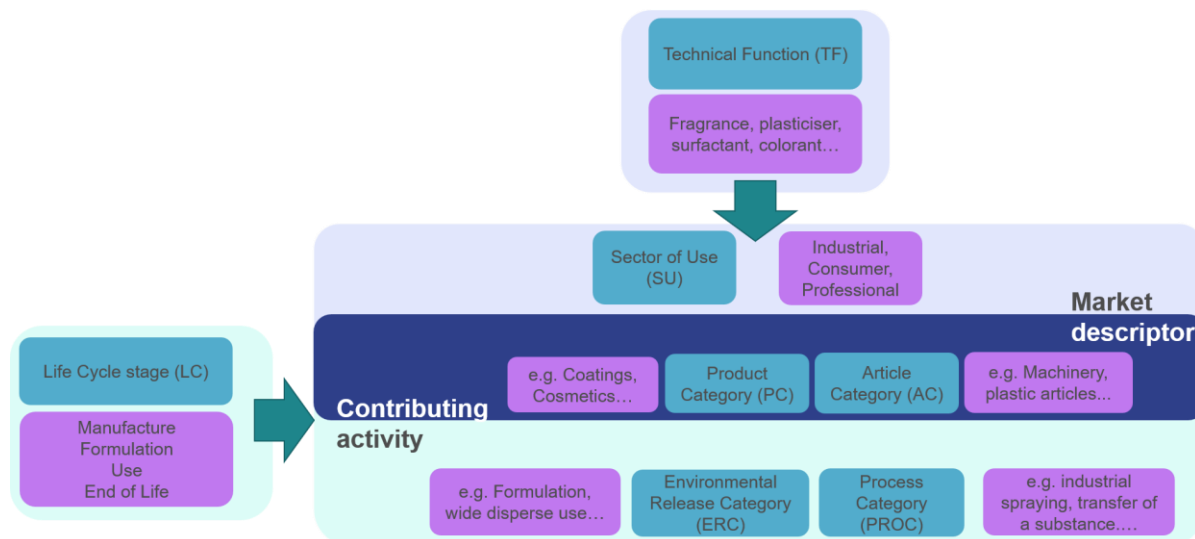
Any activity for which there is a potential for human or environmental exposure to a chemical/ material is defined under REACH (EU, 2006a) as “use”: use means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, and production of an article or any other utilisation. Therefore, in the context of the SSbD it covers the chemical/ material processing and the final product/ application stages.

REACH use descriptors

The uses are described by [The REACH use descriptor](#) (Chapter R.12) (ECHA, 2015), a system developed by ECHA to facilitate chemical risk assessment and supply chain communication. These descriptors aim to identify, describe, and communicate in a standardised format the different uses of a chemical/material life cycle stage. These descriptors have been also integrated in modelling tools such as the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC), Targeted Risk Assessment (TRA) and European Union System for the Evaluation of Substances (EUSES) and are used as input parameters to derive exposure estimates.

The logical way for describing the use case is to structure it according to the life cycle of the chemical/material. Each life cycle stage may consist of different uses. In addition, each use should be described with the following elements, see below. For each element, the practitioner could identify the information relevant for the ongoing innovation and system under assessment (Figure 38).

Figure 38. Overview of the descriptor system and information that they provide to the overall SSbD assessment



Source: JRC

- **Life cycle stage (LC):** identifies the life cycle stage of the substance and includes the four basic steps or stages in its life cycle: the manufacture, formulation (including repacking), the end-use (including industrial use, professional use, consumer use), and (article) service life.
- **Descriptor list for technical functions (TF):** this element indicates the technical function of the chemical/material meaning what does in the use (e.g. solvent, pigment). The TF provides an idea of the kind of product/article and the sector in which the chemical/material

will be used. However, the TF should be clearly distinguished from the Product Category (PC). For example, a substance can be used in anti-freeze products (PC4) without being itself an anti-freezing agent. It could be a colouring agent in the anti-freeze product.

- **The terms SU, PC and AC** (see below) provide information about the market in which the chemical/material is used
- **Sector of use (SU)** describes in which sector the chemical/material is used. This descriptor does not apply to consumer uses.
- **Product category (PC)** describes the types of chemical products in which a substance is used, the operational conditions and risk management measures to determine the level of consumer exposure.
- **Article Category (AC)** describes the type of article (including plastics and dried mixture) in which the substance has been processed.
- **Process category (PROC)** describes the application techniques or process types, the operational conditions and risk management measures to determine the level of occupational exposure for workers and professional users.
- **Environmental Release Category (ERC)** describes the broad conditions of use from an environmental perspective, based on those characteristics that give a first indication of the potential release of the substance to the environment. It determines the level of environmental exposure.
- PROCs, ERCs, PCs, and ACs provide information with regards to the contributing activities for exposure. And can be used as input parameters to derive exposure estimates in modelling tools such as [ECETOC-TRA](#) (European Centre for Ecotoxicology and Toxicology of Chemicals- Targeted Risk Assessment).

[The REACH use descriptor](#) (Chapter R.12) (ECHA, 2015), provides further guidance on how to assign the different use categories to the specific cases.

Internationally harmonised functional, product and article use categories

Although describing the uses of chemicals is an essential element in assessing exposure of humans and the environment to those chemicals during their use, approaches to categorize the uses vary between countries (i.e. ECHA, US EPA). To facilitate the exchange of information across countries, the Working Party on Exposure Assessment (Task Force on Exposure Assessment) of the OECD developed a proposal for a harmonized functional, product and article use categories. This proposal can be used as well as a tool to identify the functionality and uses of chemicals/materials for the definition of the SSbD system and that way identify the potential of exposure in a more realistic way (OECD, 2025a).

B.3. Exposure prediction tools

Typical **Conditions of use** that are needed to run a Tier 1 exposure assessment with most of the exposure tools. Working Group of the European Chapter (ISES Europe) produced a mapping of relevant available models and tools for exposure assessment. The aim is to provide guidance to enhance transparency of choices made in the selection of models, tools, and exposure-related input data and to better understand the quality of model results. The mapping covers:

- **Workers** with tools and models for exposure assessment of occupational exposure due to handling of chemicals at workplaces
- **General population** (humans) with tools and models for exposure assessment of humans via the environment and for exposure assessment due to handling of chemicals by consumers (including different sub-populations)
- **Environment**. (ecosystem) with tools and models for exposure assessment of environmental compartments due to emissions to the environment.

The innovator can benefit for the mapping and evaluation done by ISES members and identify the most appropriate tool to be used based on some descriptors like those shown in Table B1. (Schlüter et al, 2022).

Table B.1. Examples of the information on the models and tools collected for the mapping

Descriptor	Explanation of the descriptor
Exposure target	The human (sub)population (consumer, worker, general population) or environment (compartment)
Route of exposure	Route of exposure for humans (inhalation, dermal, oral) or environmental compartment (water, soil, air)
Sources of exposure	Activity or material where the substance is released or emitted and leads to exposure
Product class/chemicals/substances	Type of chemical (substance, mixture...), product class (cosmetic, pesticide...), form (vapour, particle...)
Tier/complexity:	Classification of use of the tool regarding complexity, and if applicable characterisation into tiers used in regulatory exposure assessment (tier

Source: Own elaboration adapted from Schlüter et al., 2022.

Cappucci et al., 2026 provides an overview of the features of some of these tools that were used in the application of the JRC case study report.

B.4. Information sources

Communication of information up and down the supply chain is very important to ensure the safe use of chemicals and materials throughout their entire life cycle. Safety Data Sheets are a globally recognised tool and are widely used for communicating information on chemicals and materials in the supply chain. Other tools, such as Exposure scenarios and use maps, have been newly developed in the context of specific legislation for the communication of uses. Innovators can leverage these existing tools to retrieve relevant information for their specific chemicals and materials and their uses. They may well develop and extend them further for R&I activities.

Extended Safety Data Sheets

Safety data sheets include information about the properties of existing chemicals, hazards and general instructions for handling, disposal, and transport and first-aid, firefighting, and exposure control measures.

The SDS information may be extended by exposure scenarios, which include specific information on how the exposure of workers, consumers and the environment to hazardous substances can be controlled during the specific uses identified.

This type of information can be useful to retrieve information with regards to existing chemicals/materials like the hazard classification, the occupational exposure limits and/or data related to their intrinsic properties.

Exposure Scenarios

Exposure scenarios summarise the key information contained in the chemical safety assessment, to ensure its safe use. They describe how to control the exposure to the chemical concerned of workers, consumers, and the environment, based on input parameters describing the conditions of use and the risk management measures.

An exposure scenario describes the use based on the REACH use descriptors, the conditions of use affecting the exposure, the exposure estimation ensuring the safe use and guidance to evaluate that the use is performed following these boundary conditions.

This information can be useful when substituting an existing chemical/material for an identified use or when improving the OC and RMMs. It can also support the innovator by providing real examples on how to define exposure scenarios and how to use REACH use descriptors for the identification of its own use.

Use Maps

Similar information can be retrieved from the use maps, with the difference that while the exposure scenarios are provided for specific chemicals/materials, the use maps provide this information for the common uses in a specific sector.

The “use map” concept was developed to improve the quality of information on use and conditions of use communicated up the supply chain, and likewise to improve the efficiency of this communication process.

Use maps are typically generated by downstream user sector organisations, via collecting information on the uses and the conditions of use of chemicals in their sector, in a harmonised and structured way. For this purpose, the “use map package” was developed under the CSR/ES Roadmap.

The use map gives an overview of the common uses in a specific sector using the **REACH use descriptor system**. Each use consists of several contributing activities that are also listed. For each contributing activity, a link is provided to the corresponding exposure assessment input parameters. The input includes the **conditions of use and risk management measures**, and it is provided for workers’ exposure assessment (SWED), consumers’ exposure assessment (SCED) and/ or environment exposure assessment (SPERC).

The [Use maps library](#) (ECHA, 2026) currently includes use maps developed by the following organisations:

- AISE International Association for Soaps, Detergents and Maintenance Products
- CEPE European Council of the Paint, Printing Ink and Artists’ Colours Industry
- CLE CropLife Europe
- Concawe Fuels
- Cosmetics Europe Cosmetics and personal care products

- EFCC European Federation for Construction Chemicals
- ESIG European Solvents Industry Group
- EuPC European Plastics Converters
- FEICA Association of the European Adhesive and Sealant Industry
- Fertilizers Europe
- I&P Europe, Imaging, and printing products Europe
- IFRA International Fragrance Association

The use maps templates are available to develop or update use maps by sector organisations. This harmonised practice could be extended to other kinds of chemicals/materials and product/applications. The SSbD can both benefit from use maps library to retrieve relevant information but also to develop new use maps.

ConsExpo factsheets

A similar concept to the use maps can be found in the ConsExpo factsheets. In this case the information is not linked to the REACH use descriptors but to ConsExpo.

ConsExpo is a modelling tool that can be used to estimate consumer exposure to a wide variety of products in a wide variety of circumstances.

The fact sheets are documents presenting information important for the consistent and harmonised estimation and assessment of the exposure to substances from consumer products when using ConsExpo Web (RIVM, 2026a).

In the fact sheets, information about exposure to chemical substances is compiled for certain product categories, and default parameters are given. These fact sheets describe various exposure scenarios for the specific products and set defaults for relevant exposure parameters. The fact sheets have been developed for characterising and standardising the exposure estimation, in combination with the ConsExpo Web tool.

The ConsExpo tool is based on default parameters provided in the fact sheets that represent the most conservative reasonable worst-case scenario, i.e. one which represents consumers who frequently use a certain product under unfavourable conditions.

The factsheets are also useful for any exposure estimation without the use of related exposure related software. They provide general background information that can be very useful in R&I, and likewise in the context of the SSbD.

The following fact sheets have been developed and are currently used in the ConsExpo model (RIVM, 2026a):

- [General Fact Sheet](#)
- [Air Fresheners Fact Sheet](#)
- [Cleaning products Fact Sheet](#)
- [Cosmetics Fact Sheet](#)
- [Disinfectant products Fact Sheet](#)
- [Do-It-Yourself products Fact Sheet](#)
- [Paint products Fact Sheet](#)
- [Pest control products Fact Sheet](#)
- [Children's toys Fact Sheet](#) (defaults from this fact sheet are not included in the ConsExpo Web database).

CPDat (Chemical and Products Database)

Another tool that can be used to retrieve information on chemicals/materials for the exposure assessment is the CPDat (Chemical and Products Database). This database was developed by the US Environmental Protection Agency (EPA). It contains information mapping more than 49,000 chemicals to a set of terms categorizing their usage or function in 16,000 consumer products (e.g. shampoo, soap) types based on what chemicals they contain. The database is a part of EPA's Computational Toxicology (CompTox) Dashboard and contains data from other EPA databases including CPCat, CPCPdb and FUse. CPDat also contains data from non-targeted analysis of chemicals performed on different consumer products and from new product composition data that is publicly available (US EPA, 2026a; Isaacs et al, 2020)

RMM library

At the start of the REACH implementation, the European chemicals trade association, Cefic, set up a library of RMMs, containing a first structured collection of available RMMs for the different target groups and exposure routes in exposure assessment. This library addresses the control of exposure to consumers, environment, and workers. The information in the library relates to sectors, product groups, processes, or single horizontal measures like personal protective equipment (PPE).

The [RMM library](#) is an EXCEL spreadsheet that contains:

- A practical guide to use the library
- The library containing RMMs / OCs and details of their effectiveness; and
- Lists of information sources for consumers, environment, and occupational measures.

Corresponding to the library, ECHA published the Guidance Chapter R.13, providing an initial concept on how to define risk management in the context of a REACH exposure assessment, in turn providing additional guidance on the RMM library (ECHA, 2012b).

A further developed library, the [Integrated Risk Management Measures Library \(ECEL 3.0\)](#) is available at the TNO's (Netherlands Organisation for Applied Scientific Research) Diamonds platform (CEFIC, 2026).

OECD SAAToolbox

The OECD Substitution and Alternatives Assessment Toolbox (SAAToolbox) compiles resources relevant to chemical selection including substitution and alternatives assessment and OECD SSIA (Safe(r) and Sustainable Innovation Approach) for nano-enabled and other emerging materials. It includes tools and data sources with a subset focused on chemicals, materials, processes and products. It addresses attributes such as hazard, exposure, life cycle and economic and social considerations. The SAAToolbox also contains topical frameworks, guides, toolkits and product rating systems developed by various organisations. Case studies on substitution conducted by manufacturers, academic institutions, NGOs or government bodies are compiled. (OECD, 2026c.).

B.6. Checklist

This section presents an example of a checklist for the safety assessment, considering the relevant aspects covered in Section 4.

Table B.2. Example of a possible guiding checklist for the safety assessment.

Problem Formulation	☐ Goal/Purpose of the assessment clearly defined ☐ Decision context identified (screening / redesign / comparison / compliance) ☐ Assessment scope defined (chemical/material, life cycle stages) ☐ Relevant populations identified (workers, consumers, general public) ☐ Environmental compartments identified (air, water, soil, sediment) ☐ Relevant hazard endpoints identified ☐ Exposure routes identified (oral, dermal, inhalation) ☐ Assessment type defined (qualitative / semi-quantitative / quantitative) ☐ Decision criteria defined (e.g. RCR < 1, improvement vs baseline) ☐ Acceptable uncertainty level defined ☐ Key assumptions documented	
Chemical/ Material Characterisation	☐ Chemical/material identity defined ☐ Chemical/material type identified (mono-constituent, UVCB, mixture, material, nanomaterial, multicomponent) ☐ Composition and impurities described ☐ Physico-chemical properties available ☐ Fate properties available ☐ Stability and transformation assessed ☐ Relevant form(s) during use identified ☐ Behaviour in relevant media considered ☐ Component-based approach applied where relevant ☐ Characterisation uncertainties documented	
Hazard Identification	Tier 0-1 – Screening	☐ Existing CLP classification reviewed ☐ Safety Data Sheet (SDS) assessed ☐ Regulatory database information checked ☐ QSAR / read-across applied where appropriate ☐ “Red flags” identified
	Tier 2 – Refinement	☐ In vitro data available or generated ☐ NAMs applied and justified ☐ Endpoint-specific data reviewed
	Tier 3 – Comprehensive	☐ IATA applied where needed ☐ In vivo data available and justified
Hazard Characterisation	☐ Data quality assessed ☐ Dose–response relationship established (NOAEL, LOAEL, LD50, LC50, BMD) ☐ DNEL derived (human health) ☐ DMEL derived (non-threshold effects, if relevant) ☐ PNEC derived (environmental compartments) ☐ OEL available and considered (if applicable)	

	☐ Assessment factors justified ☐ Population-, route-, and duration-specific values derived
Exposure Estimation	Use and Exposure Scenarios ☐ Life cycle stages identified ☐ Sector of use (SU) defined ☐ Product category (PC) defined ☐ Process category (PROC) defined ☐ Environmental release category (ERC) defined ☐ Operational conditions (OCs) described ☐ Exposure routes identified (oral, dermal, inhalation) ☐ Concentration defined ☐ Frequency and duration defined ☐ Risk management measures (RMMs) identified ☐ Worker exposure estimates calculated ☐ Consumer exposure estimates calculated ☐ Environmental exposure (PEC) estimates calculated ☐ Key exposure drivers identified Exposure Estimation ☐ Tier 1 conservative screening completed ☐ Tier 2 refined modelling applied ☐ Tier 3 monitoring or measured data used (if available)
Risk Characterisation	☐ RCR calculated for human health ☐ RCR calculated for environment ☐ RCR < 1 confirmed OR refinement triggered ☐ Risk drivers identified
Uncertainty and Documentation	☐ Data gaps identified ☐ Key uncertainties documented ☐ Sensitivity or scenario analysis performed ☐ Conservative assumptions justified ☐ Expert judgement documented ☐ Overall confidence level stated ☐ Transparency and traceability ensured
Outcome	☐ Safety assessment complete for current innovation stage/SSbD iteration ☐ Conclusions aligned with problem formulation ☐ Conditions for safe use defined ☐ Follow-up actions identified ☐ Review/update triggers defined

Source: JRC

Annex C: Background information and terminology to read the Environmental Sustainability Assessment

The inclusion of an LCA approach during the innovation process can be beneficial **to quantify the impact of the design goals and the implementation of the design principles, and the (environmental) hotspots for further improvement.**

For the fundamental full knowledge and terminology commonly referred to in LCA methodology and regarding the Full LCA Product Environmental Footprint (PEF) method, please consult the documents are freely available online: [European Platform on LCA | EPLCA \(europa.eu\)](https://eplca.europa.eu) (EC, 2024). Additional terminology in this Section refers to the “tiered” type of LCAs, progressively refining the LCA over iterations, related to both the data obtained – or available – and the level of assessment undertaken.

Each progression being a successive “Tier”, as explained below:

Environmental Sustainability Assessment (ESA): includes the whole approach of assessing the environmental aspects via the tiered approach, which includes both screening assessment and tiered LCA.

Functional unit: quantified performance of a chemical/material required to provide a specific function and is the basic requirement for meaningful comparisons in LCA. The functional unit of an LCA can be defined answering to the questions: What is the function/service provided by the chemical/material? To which extent should this function be provided? How long? And how well?

Full LCA: it refers to an LCA that follow the recommendation in the PEF.

Indicator: an indicator is a pointer or index that indicates something. In LCA analysis it is used to measure the adoption of a specific design principle, or to measure an impact category in LCA. For instance, kgCO₂ eq. is an indicator for Climate Change. Another indicator for Climate change may be Global Warming Potential (GWP). Similarly, to measure the level of application of design principles related to circularity, possible indicators that may be utilised are the Value-based resource efficiency indicator (VRE), Material Circularity Indicator (MCI), or the Recycled Content.

Innovation technology: all the innovation in the scope of the SSbD, for instance, chemical/material innovation, chemical/material substitution, or chemical/material-related process and product improvements.

Intermediate products: the FU is more difficult to define as it may often fulfil multiple functions and the whole life cycle of the product is not known. Therefore, a declared unit should be applied, for example, mass (kilograms) or volume (cubic meters) (EC, 2021)

Prospective LCA: an LCA methodology suitable to innovation processes, which estimates the associated environmental impacts before the new/redesigned chemical or material is placed on the market, i.e. referring to ex-ante evaluations.

Reference: a standard value against which any comparison may be made. In the context of the SSbD, the reference can be either a benchmark, a target, or the status quo of the specific innovation.

Representative system: SSbD system – that may be virtual or real – used for the comparative assessment as the initial starting point of the innovation, representing the current situation to be

improved upon. The information of the representative system comes from either literature or engagement with the actors of the life cycle.

Screening assessment: Early-stage assessments that include the evaluation of indicators linked to the implementation of the design principles.

Simplified LCA: full LCA with several assumptions and simplifications due to some unknown aspects.

Streamlined LCA: iterative modelling of the LCA that goes from a simplified LCA to a more complete assessment but lacking the full detail of a PEF-compliant LCA or equivalent.

Tiered ESA: overall approach applicable in the context of the SSbD framework, which comprises the progressively more developed LCA tiers of a simplified, a streamlined, and full LCA.

For **additional information and terminology**, please check Annex I of the SSbD framework.

Annex D: Definition of the chemical benchmark

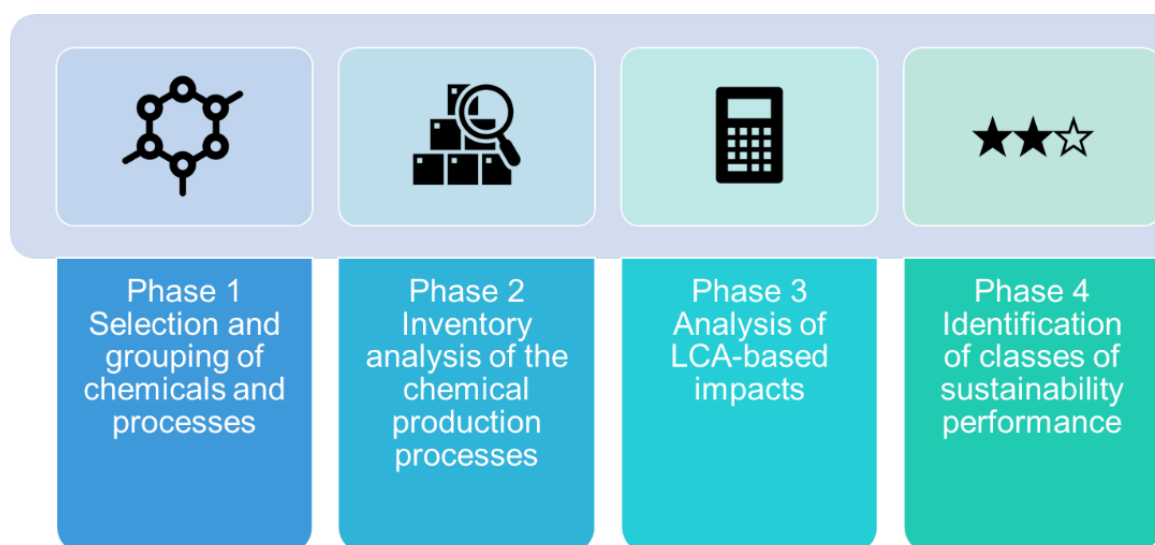
The definition of a benchmark represents a part of the ESA reference system definition. More specifically, the benchmark is defined for the **basic organic chemicals**, being those used for any other fine chemicals in the supply chain. Depending on the availability of data, a future benchmark(s) could encompass also specialty chemicals, i.e. low product volume chemicals characterised by their use for specific applications.

Once the group of chemicals has been defined (Phase 1), the core of the activity was to undertake the **analysis of the inventory and the impacts** of the selected chemicals, considering a cradle-to-gate system boundary (Abbate et al. 2026b). Each chemical was mapped, including its associated Life Cycle Inventory information (Phase 2), comprising, for example: the input and output flows to/ from the production processes, and impact assessment information via the impact categories, as detailed in the PEF Recommendation (Phase 3). This activity is necessary to identify the **benchmark**. Based on the benchmark, **classes of sustainability performance** of chemicals were identified (in Phase 4).

Limitations:

- The production processes and the related flows depend on the location of the particular production site. Production processes of the same chemical(s), but located in two production different sites (e.g., within the EU/ extra-EU) might use different input flows and generate different emissions. However, this limitation is already acknowledged when performing an LCA study and when using a commercially available “general” LCA database to map background processes.
- Availability of the level of aggregation of the datasets.
- The current benchmark reflects the average impacts of bulk chemicals, referred to 1 kg of chemical produced. This approach does not take into consideration the functionality of the chemicals.

Figure 39. Proposed preliminary phases for the identification of a chemical benchmark



Source: JRC

Annex E: Indicators for the process-related sustainability assessment

Table E1. Indicative list of possible indicators for the different tiers

Category of indicators	Simplified -> Screening Process indicators	Medium -> Worst case Process/ Emission indicators	High -> Impact Quality/Impact indicators
Air	Screening of direct process emissions	Chemical agents, for example: - Pollutants, such as NO_x, SO_x, PM, CO, VOCs, HMs. - Odours Physical agents, for example heat, noise or radiations Example of index: Industrial Emission Index	- Semi-quantitative estimation of the impact on air quality, can be done considering the background chemical status of air compartment. - Indicators and indexes can be chosen to estimate the quality of the air compartment, for example estimating or measuring the chemical concentration against regulatory thresholds but also selecting bio-indicators to estimate the impact on sensitive species/populations (e.g.: <i>lichens</i>).
Water & Effluent	Screening of direct process emissions Water consumption	Chemicals agents, for example: - Pollutants, such as HMs, persistent organic contaminants, - nutrients load in wastewater (N, P); - Chemical /Physical parameters, such as T, pH, salinity, BOD/COD etc. Physical agents, for example heat, noise or radiations Biological agents release should be also considered, such as common pathogens but also possible alien species or OGM Example of index: Industrial Emission Index	- Semi-quantitative estimation of the impact on water quality, can be done considering the background chemical and ecological status of surface water bodies, such as river and lake, including sediments. For groundwater, it should be considered the chemical/biological status but also the hydric stress due to the water consumption. - For surface water, indicators and indexes can be chosen to estimate the quality, for example selecting bio-indicators to estimate the impact on sensitive species/populations, or index representing the functionality of water ecosystem, varying from good to poor. For groundwater, quantitative and quality indicators can be chosen to estimate the impact on availability of the water resource and chemical/biological quality.
Soil & Land	Soil consumption	Consider the possibility of indirect emissions to soil as consequence of air and water emission, listed above	- Semi-quantitative estimation of the impact on soil, can consider the background chemical and ecological status of the soil, as well as the type of land use. - Indicators and indexes can be chosen to estimate the quality off soil compartment, for example selecting bio-indicators to estimate the impact on sensitive species/populations (for example <i>earthworms</i>) or index representing the functionality of soil ecosystem, varying from good to poor.
Biodiversity & Habitat	-	Consider the possibility of direct/ indirect exposure of ecosystem to chemical,	- Semi-quantitative estimation of the impact on biodiversity and habitat, can consider the Integration of the above indicators, also

Category of indicators	Simplified -> Screening Process indicators	Medium -> Worst case Process/ Emission indicators	High -> Impact Quality/Impact indicators
		Biological and physical agents emitted from the industrial process	depending on the presence of protected or sensitive area(s) and their capacity to recover. - Different quality indicators can be chosen, for example estimating the impact in terms of biodiversity loss or habitat fragmentation, but also change in the land use, varying from good to poor.
Climate Change	Direct GHGs process emissions	Gate-gate climate change impacts (i.e. including indirect emissions)	Cradle-to-gate or full LCA
Resource Efficiency	Material Intensity index (kg materials / kg product) Net water consumption (m ³ /kg product) Energy consumption (MJ/ kg product)	-	-
Waste & Circularity	Waste generation (kg/kg product)	-	-

Source: JRC

Annex F. Data sources, reference scales and monetisation factors for the socio-economic assessment

Table F1. List of social indicators (examples), possible data sources of secondary data and related level of aggregation

Examples of indicators	Data source	Level of aggregation
Proportion of children engaged in economic activity (%)	ILO Child Labour Statistics (CHILD) (ILO, 2026a)	Country Male, female, total
Global Slavery Index	Walk Free Foundation (Walk Free, 2026)	Country (prevalence of forced labour, government response, vulnerability)
Goods produced by forced labour	US Department of Labor (US Department of labor, 2026)	Product Country
Average monthly earnings of employees by sex and economic activity	ILOSTAT Wages and Working Time Statistics (COND) (ILO, 2026b)	Country Sector (ISIC Rev 3 and ISIC Rev 4 classifications of economic activities)
Mean weekly hours worked per employed person by sex and economic activity	ILOSTAT Wages and Working Time Statistics (COND)	
Gender wage gap (%) Proportion of women in senior and middle management positions (%)	SDG Labour Market Indicators (ILOSDG) (ILO, 2026c)	Country
Level of national compliance with labour rights (freedom of association and collective bargaining)	SDG Labour Market Indicators (ILOSDG) (ILO, 2026d)	Country

Examples of indicators	Data source	Level of aggregation
Preventive measures and emergency protocols exist regarding: i) accidents and injuries, ii) pesticide and chemical exposure Adequate general occupational safety measures	Only primary data	
Fatal/non-fatal occupational injuries per 100'000 workers	ILO Occupational Safety and Health Statistics (OSH) (ILO, 2026e)	Country Sector (ISIC Rev 2, Rev 3 and Rev 4 classifications of economic activities)
Organisation efforts to strengthen community health (e.g. through shared community access to organisation health resources) Management effort to minimize use of hazardous substances and control of structural integrity	Only primary data	
Contribution of the product/service/organisation to economic progress (e.g. annual growth rate of real GDP per employed person)	UN National Accounts Statistics: Analysis of Main Aggregates (UN, 2026)	Country Sector (ISIC classification)
Average proportion of skilled workers, out of all workers (%) Knowledge intensive jobs (% high-skilled employees (ISCO level 3-4) /total employees required for a unit of production)	World Bank Enterprise Survey	
Involvement in technology transfer program Projects partnerships in research and development Investments in technology development/technology transfer Patent growth rate in % of this technology for a defined period (e.g. 5 years).	Only primary data	
Ratio of training investment per employee vs. industry benchmarks. Qualitative assessment of the extent to which the company contributes to skill development for the community at large.	Only primary data	

Source:JRC

Table F2. Reference scales examples for the socio-economic indicators

Socio-economic aspect	Examples of indicators	Reference scales	Source
Risk of child labour in the supply chain	% of children in employment (age 7-14)	very high risk: >20 high risk: 10-20 medium risk: 5-10 low risk: 2.5-5 very low risk <= 2.5	Loubert et al. 2023
Risk of forced labour in the supply chain	Risk of forced labour in the country (cases per 1,000 inhabitants)	very high risk: >16 high risk: 12-16 medium risk: 8-12 low risk: 4-8 very low risk <4	Loubert et al. 2023
Fair salary	Living wage, per month Sector average wage, per month	y, ratio Salary/Living wage 0 < y <1 very high risk 1 ≤ y < 1.5 high risk 1.5 ≤ y < 2 medium risk 2 ≤ y < 2.5 low risk 2.5 ≤ y very low risk	Loubert et al. 2023
Working time	Hours of work per employee, per week	very high risk: <20 and >60 high risk: 20 - <30 and 55 - <60	Loubert et al. 2023

Socio-economic aspect	Examples of indicators	Reference scales	Source
		medium risk: 30 - <40 and 48 - <55 low risk: 40 - <48	
Equal opportunity and discrimination	Gender wage gap (%)	very high risk: $\geq 30\%$ and $\leq -30\%$ high risk: 20% - <30% and -20% - >-30% medium risk: 10% - <20% and -10% - >-20% low risk: 5% - <10% and -5% - >-10% very low risk: 0% - <5% and 0% - >-5%	Loubert et al. 2023
Freedom of association and collective bargaining	Right of association (ordinal scale) Right of collective bargaining (ordinal scale) Right to strike (ordinal scale)	very high risk: 0 high risk: 1 low risk: 2 very low risk: 3	Loubert et al. 2023
	Trade union density (% of employees organized in trade unions)	very high risk: 0-20% high risk: >20-40% medium risk: >40-60% low risk: >60-80% very low risk: >80%	Loubert et al. 2023
	Preventive measures and emergency protocols exist regarding pesticide and chemical exposure Adequate general occupational safety measures	Qualitative reference scale to be developed by the practitioner based on - the management practices and strategies the organisation guarantees in terms of health and safety of its own workers and in its community of suppliers. - the maintenance and promotion of workers' health and working capacity. - the improvement of working environment and work to become conducive to safety and health and development of work organisations and working cultures in a direction which supports health and safety at work - the status of prevention measures and management practices; the extent to which the management maintains or improves the safety and overall health status of the workers. (E.g. investments in prevention measures, trainings, procedure in place to collect complaints regarding its own workers; investments in partnerships that improve the health and safety in the region the company purchases from).	Loubert et al. 2023

Socio-economic aspect	Examples of indicators	Reference scales	Source
Presence of safety measures	Preventive measures and emergency protocols exist regarding accidents and injuries (cases of violation per 100,000 employees)	very high risk: > 0.0565 high risk: 0.0215 - < 0.0565 medium risk: 0.0095 - < 0.0215 low risk: 0.0025 - < 0.0095 very low risk: < 0.0025	Loubert et al. 2023
Accidents at work	Rate of non-fatal accidents at workplace (cases per 100.000 employees and year)	very high risk: ≥ 3000 high risk: 2250 – 3000 medium risk: 1500 – 2250 low risk: 750 – 1500 very low risk: 0 – 750	Loubert et al. 2023
	Rate of fatal accidents at workplace (cases per 100.000 employees and year)	very high risk: ≥ 40 high risk: 25 -40 medium risk: 15-25 low risk: 7.5 -15 very low risk: 0 -7.5	Loubert et al. 2023
Safe and healthy living conditions	Organisation efforts to strengthen community health (e.g. high risk through shared community access to organisation health resources) Management effort to minimize use of hazardous substances Management oversight of structural integrity	Qualitative reference scale to be developed by the practitioner based on: - The extent to which the company or facility works to prevent and mitigate adverse impacts or enhance positive impacts on the health and safety of the local community - Evidence that the company invests and have procedure in place to communicate potential health and safety impacts of their operations to surrounding communities. - Institution of environmental risk management systems for preventing, mitigating and controlling health damage from operations.	Zanchi et al. 2023
Contribution to GDP	Contribution of the product/service/organisation to economic progress (e.g. annual growth rate of real GDP per employed person; sector level: % of GPD)	no opportunity: 0-<1 low opportunity: 1-10 medium opportunity: >10-25 high opportunity: >25	Loubert et al. 2023
Creation of knowledge-intensive employment	Knowledge intensive jobs (% high-skilled employees (ISCO level 3-4) /total employees required for a unit of production)	< 20% No opportunity/risk opportunity 20% – 39% Low opportunity 40% – 59% Moderate opportunity ≥ 60% High opportunity	Authors' proposal
Technology potential	Patent growth rate in % of this technology for a defined period (e.g. 5 years).	≥ 20% High opportunity (High innovation potential) 5% – 19% Moderate opportunity 0% – 4% Moderate risk < 0% (decline) High risk	Authors' proposal

Socio-economic aspect	Examples of indicators	Reference scales	Source
Skill shortages risk	Ratio of training investment per employee vs. industry benchmarks.	Ratio (Company / Industry Benchmark) ≥ 1.2 Low risk / Positive contribution 0.8 – 1.19 Moderate risk 0.5 – 0.79 Elevated risk < 0.5 High risk	Authors' proposal

Source: JRC

Table F3. Examples of reference scales using qualitative information as developed in Zanchi et al. 2023)

Social topic		Discrimination and equal opportunities	Forced labour
level -2	definition	Incidents are reported revealing discrimination is frequently occurring or is part of the companies' culture and procedures.	Evidence indicates that there is a substantial risk that forced labour is present in the company. Incidents of forced labour have been discovered in the company, and a corrective action plan with a clear timeline for completion has not been developed.
	performance indicators	- Complaints, lawsuits and other signals that may signal issues - Absence of positive information while the company is in an area where this situation often occurs according to statistics.	- Complaints, lawsuits and other signs that may indicate issues. - Absence of positive information, while the company is in an area where this situation often occurs according to statistics.
level -1	definition	Incidents of discrimination have been discovered; the company or facility has established a corrective action plan with a clear timeline for completion	Incidents of forced labour have been discovered in the company or facility and a corrective action plan with a clear timeline for completion has been developed.
	performance indicators	- While the company is in an area or sector where this situation often occurs according to statistics, there is evidence that the company has started to address the situation with a clearly defined timeline. - The number of complaints, lawsuits and other signals have been significantly reduced during the last 3 years.	- While the company is in an area where this situation often occurs according to statistics, there is evidence that the company has started to address the situation with a clearly defined timeline. - The number of complaints, lawsuits and other signals have been significantly reduced during the last 3 years.
level 0	definition	The company or facility has a management system in place to enforce the non-discrimination policy in its company	There are no reports or indications that the company uses forced labour, and all workers are employed under reasonable and documented conditions that prohibit the withholding of all or part of the worker's wages, benefits, property or original documents.

	performance indicators	Wage slips or wage records of workers confirm equal pay for work of equal value. - Established grievance mechanisms for workers to report a complaint or raise concerns about any actions that violates non-discrimination policy. - The company has fully committed to the Global Compact principles and explicitly communicated this to all stakeholders	- Documentation of the terms and mechanisms to monitor and improve the position of the worker are in place, such as “speak up” line, training and awareness sessions, while there are no indications that the company or facility uses forced labour. - The company has fully committed to the Global Compact principles and explicitly communicated this to all stakeholders.
level + 1	definition	The company or facility has a management system place that pro-actively promotes non-discrimination in its organization, its subcontractors and its tier 1 suppliers., for instance by at least two of the following: 1. Trainings/education programs and events to raise awareness 2. Employee committees to address certain issues 3. Speak-Up Line 4. Commitments from tier 1 suppliers	The company or facility has a management system that successfully eliminates the use of forced labour in its own organization, its subcontractors and its first-tier suppliers.
	performance indicators	- Public statements by the company, workers or unions - Description of the management system objectives and timeline	- Evidence that the company conducts due diligence in relation to its procurement practices within its own organization and its subcontractors, as well as evidence that the company requires its subcontractors to conduct due diligence in relation to its procurement practices. - Evidence that the company requires subcontractors and their suppliers to implement a policy prohibiting the withholding of all or part a worker's salary, benefits, recruitment fees, property or original documents, such as identity documents.
level +2	definition	The company or facility has a management system in place that pro-actively promotes non-discrimination in its organisation and the entire supply chain. The commitments, performance, progress and effectiveness of programmes are reported publicly. The top management of the company or facility have publicly recognised non-discrimination as a key priority.	The company has made the elimination of forced labour in its own organization and throughout its value chain, including its customers, a top priority and can demonstrate the success of its approach.

	performance indicators	• Investments and participation in public private initiatives and NGOs that effectively deal with the issue. • Statements from credible authorities' organisations such as NGOs and unions	• The company actively and publicly engages and invests in public-private partnerships that have a proven track record in addressing the root causes of forced labour throughout its value chain. • Recognition by independent NGOs and credible news reports.
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Source: Zanchi et al., 2023

Table F4. Set of monetary valuation coefficients as proposed in Gama Caldas et al. (2024)

Impact category		Unit of measure	Value
1	Climate change, total	€ ₂₀₁₉ /kg CO ₂ eq.	1.00x10 ⁻¹
2	Ozone depletion	€ ₂₀₁₉ /kg CFC-11 eq.	5.55x10 ⁺¹
3	Human toxicity, cancer	€ ₂₀₁₉ /CTUh	1.66x10 ⁻⁵
4	Human toxicity, non-cancer	€ ₂₀₁₉ /CTUh	9.19x10 ⁻⁵
5	Particulate matter	€ ₂₀₁₉ /disease incidence	7.28x10 ⁺⁵
6	Ionising radiation, human health	€ ₂₀₁₉ /kBq U ₂₃₅ eq.	-
7	Photochemical ozone formation, human health	€ ₂₀₁₉ /kg NMVOC eq.	1.20x10 ⁰
8	Acidification	€ ₂₀₁₉ /mol H ⁺ eq.	3.50x10 ⁻¹
9	Eutrophication, terrestrial	€ ₂₀₁₉ /mol N eq.	-
10	Eutrophication, freshwater	€ ₂₀₁₉ /kg P eq.	1.95x10 ⁰
11	Eutrophication, marine	€ ₂₀₁₉ /kg N eq.	3.27x10 ⁰
12	Ecotoxicity, freshwater	€ ₂₀₁₉ /CTUe	3.89x10 ⁻⁵
13	Land use	€ ₂₀₁₉ /pt	1.78x10 ⁻⁴
14	Water use	€ ₂₀₁₉ /m ³ water eq. of deprived	5.08x10 ⁻³
15	Resource use, minerals, and metals	€ ₂₀₁₉ /kg Sb eq.	-
16	Resource use, fossils	€ ₂₀₁₉ /MJ	-

Source: Gama Caldas et al., 2024

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